# **Chapter 5 Acute Care Facilities and Services Overview**

Mississippi had 112 non-federal medical/surgical hospitals in FY 2016, with a total of 13,155 licensed acute care beds (plus 573 beds held in abeyance by MSDH). This total includes one OB/GYN hospital but excludes one rehabilitation hospital with acute care beds and Delta Regional Medical Center-West Campus which is licensed as an acute care hospital but is used primarily for other purposes. This total also excludes long-term acute care (LTAC), rehabilitation, psychiatric, chemical dependency, and other special purpose beds. In addition, numerous facilities provide specific health care services on an outpatient basis. Some of these facilities are freestanding, others are closely affiliated with hospitals. Such facilities offer an increasingly wider range of services, many of which were once available only in inpatient acute care settings. Examples include diagnostic imaging, therapeutic radiation, and ambulatory surgery.

#### 500 General Medical/Surgical Hospitals

When calculating the occupancy rate using total licensed bed capacity, the overall occupancy rate drops to 36.27 percent. Using these statistics and 2023 projected population totals, Mississippi had a licensed bed capacity to population ratio of 4.19 per 1,000 and an occupied bed to population ratio of 1.52 per 1,000. Table 5-1 shows the licensed Mississippi hospital beds by service areas.

These statistics indicate an average daily census in Mississippi hospitals of 4768.36 leaving approximately 8377.64 unused licensed beds on any given day. Eighty (80) of the state's hospitals reported occupancy rates of less than 40 percent during FY 2016.

Mississippi requires Certificate of Need (CON) review for all projects that increase the bed complement of a health care facility or exceed a capital expenditure threshold of \$2 million. The law requires CON review regardless of capital expenditure for the construction, development, or other establishment of a new health care facility, including a replacement facility; the relocation of a health care facility or any portion of the facility which does not involve a capital expenditure and is more than 5,280 feet from the main entrance of the facility; and a change of ownership of an existing health care facility, unless the MSDH receives proper notification at least 30 days in advance. A health care facility that has ceased to treat patients for a period of sixty (60) months or more must receive CON approval prior to reopening. A CON is required for major medical equipment purchase if the capital expenditure exceeds \$1.5 million and is not a replacement of existing medical equipment.

A statewide glut of licensed acute care beds complicates planning for community hospital services. There are far more hospital beds than needed. The average use of licensed beds has been less than fifty percent (50% percent) in recent years. With few exceptions, the surplus is statewide. The continued presence of surplus hospital beds in all planning districts, and in nearly all counties with acute care hospitals, raises a number of basic planning questions:

- Does the "carrying cost" of maintaining unused beds raise operating cost unnecessarily?
- Do the surpluses, and any associated economic burdens, retard the introduction of new and more cost effective practices and services?

- Do existing services providers maintain unwarranted surpluses to shield themselves from competition, as argued by some potential competitors?
- Should the space allocated to surplus beds be converted to other uses, particularly if doing so
  would avoid construction of new space, or facilities, to accommodate growing outpatient
  caseloads?
- Do the large surpluses mask need for additional services and capacity in some regions and reduce the sensitivity and responsiveness of planners and regulators to these legitimate community needs?
- Do the continuing surpluses, and the view of them by stakeholders and other interested
  parties, create an environment that invites policy intervention by legislators and other
  responsible parties?

These questions are unusually difficult to answer definitively. The fact that they arise frequently suggest the importance of reducing excess capacity where it is possible to do so and is not likely to result in problematic consequences. MSDH urges each hospital to voluntarily reduce the licensed bed capacity to equal its average daily census plus a confidence factor that will assure that an unused hospital bed will be available on any given day.

Table 5-1 Licensed Short-Term Acute Care Hospital Beds by Service Area FY 2016

	Licensed	Abeyance	Average	Occupancy	Average
Facility	Beds	Beds	Daily Census	Rate	Length of Stay
General Hospital Service Area 1	688	18	279.45	40.62	4.83
Alliance Healthcare System, Inc.	40	10	7.85	19.62	6.11
Baptist Memorial Hospital - DeSoto	309		145.51	47.09	4.13
Methodist Healthcare Olive Branch Hospital*	67		16.94	25.29	3.61
North Oak Regional Medical Center - Senatobia	76		11.59	15.25	5.04
Panola Medical Center	102	18	31.21	30.60	4.61
Parkwood Behavioral Health System	94	10	66.35	70.59	8.90
General Hospital Service Area 2	1,151	45	504.01	43.79	5.12
Baptist Memorial Hospital - Booneville	104	10	13.70	13.17	9.70
Baptist Memorial Hospital - Union County	145		23.52	16.22	2.89
Laird Hospital	25		1.85	7.41	3.22
Magnolia Regional Health Center	200		84.66	42.33	4.22
North Mississippi Medical Center	577		324.84	56.30	5.04
North Mississippi State Hospital	50		46.38	92.76	29.54
Pontotoc Health Services	25		1.46	5.83	29.34
	25	45		30.40	
Tippah County Hospital	48	43	7.60 5.72		5.54
Tishomingo Health Services, Inc.	_	41		11.92 <b>29.78</b>	3.13 <b>4.92</b>
General Hospital Service Area 3	983	41	292.73		
Allegiance Speciality Hospital of Greenville	39	1	22.21	56.94	18.62
Bolivar Medical Center	164	1	29.76	18.15	3.76
Delta Regional Medical Center	195		63.61	32.62	4.71
Delta Regional Medical Center- West Campus	67	40	9.53	14.23	4.95
Greenwood - AMG Specialty Hospital	40		19.82	49.55	24.12
Greenwood Leflore Hospital	188		60.18	32.01	4.03
Medical/Demtal Facility at Parchman	56		37.93	67.73	12.05
North Sunflower Medical Center	35		22.90	65.44	7.52
Northwest Mississippi Medical Center	171		33.13	19.38	3.88
South Sunflower County Hospital	49		15.13	30.88	4.05
Tallahatchie General Hospital	18		0.74	4.09	1.58
General Hospital Service Area 4	1,255	49	324.39	25.85	4.04
Baptist Memorial Hospital - North Mississippi	204		71.26	34.93	4.06
Baptist Memorial Hospital - Calhoun	25	4	2.17	8.69	3.34
Baptist Memorial Hospital-Golden Triangle	307		88.73	28.90	4.10
Choctaw Regional Medical Center	25	0	1.55	6.21	3.14
Clay County Medical Corporation	54		8.99	16.65	3.00
Diamond Grove Center	25		20.73	82.94	9.55
Gilmore Memorial Hospital	95		19.67	20.70	3.14
Monroe Regional Hospital	35		8.21	23.46	13.34
Noxubee General Critical Access Hospital	25		6.12	24.47	3.65
Oktibbeha County Hospital Trace Regional Hospital	90 84	0	20.98 10.25	23.32 12.20	3.33 10.98
Tyler Holmes Memorial Hospital	25		3.06	12.20	3.41
University of Mississippi Medical Center- Grenada	156	4	27.79	17.81	4.17
Webster Health Services, Inc.	38		22.53	59.30	6.17
Winston Medical Center	41	41	10.41	25.39	4.42
Yalobusha General Hospital	26		4.67	17.96	3.39

Table 5-1 (continued)
Licensed Short-Term Acute Care Hospital Beds by Service Area
FY 2016

Facility	Licensed Beds	Abeyance Beds	Average Daily Census	Occupancy Rate	Average Length of Stay
General Hospital Service Area 5	4,693	229	1,690.37	36.02	5.21
Baptist Medical Center - Attala, Inc.	25	46	3.92	15.67	1.00
Baptist Medical Center - Leake, Inc.	25		5.50	22.01	3.80
Baptist Medical Center - Yazoo, Inc.	25		5.93	23.70	4.38
Brentwood Behavioral Healthcare of MS	105		71.03	67.65	9.35
Claiborne County Hospital	32		4.53	14.14	12.15
Copiah County Medical Center	25	10	13.29	53.16	6.57
Holmes County Hospital and Clinics	25	10	2.35	9.41	2.94
Magee General Hospital	64	20	10.35	16.16	3.99
Merit Health Central	304	143	80.92	26.62	4.86
Merit Health Madison	67		11.72	17.49	3.38
Merit Health Rankin	134		35.56	26.53	3.31
Merit Health River Oaks	130		37.75	29.04	5.00
Merit Health River Region Merit Health Woman's Hospital	321 109		80.01 10.16	24.93 9.32	5.05 2.66
Mississippi Baptist Medical Center	541		246.46	45.56	4.38
Mississippi Methodist Rehabilitation Center	44		0.00	0.00	0.00
Mississippi State Hospital	1,347		171.95	12.77	57.69
Oak Circle Center	60		26.91	44.85	37.87
Patients' Choice Medical Center of Smith County	29		5.60	19.31	12.96
Promise Hospital of Vicksburg	35		27.82	79.48	25.84
Regency Hospital of Hattiesburg	33		27.61	83.68	27.55
S.E. Lackey Memorial Hospital	35		17.82	50.90	5.34
Select Specialty Hospital - Belhaven, LLC	25		18.59	74.36	32.67
Select Specialty Hospital - Jackson	53		40.27	75.97	25.29
Scott Regional Hospital	25		2.84	11.35	3.52
Sharkey - Issaquena Community Hospital	29		6.07	20.94	4.80
Simpson General Hospital	35		11.22	32.06	6.38
St. Dominic-Jackson Memorial Hospital	500		337.82	67.56	3.73
University of Mississippi Medical Center	479		372.26	77.72	4.69
Whitfield Medical Surgical Hospital	32	11	4.13	12.92	8.08
General Hospital Service Area 6	1,088	111	490.01	45.04	5.48
Alliance Health Center**	146	111	64.34	44.07	8.26
		71	134.60	51.77	4.06
Anderson Regional Medical Center	260	/1	6.81		
Anderson Regional Medical Center South Campus	49			13.89	12.24
East Mississippi State Hospital	151	6	114.21	75.63	8.02
H.C. Watkins Memorial Hospital	25		2.76	11.02	3.90
John C. Stennis Memorial Hospital	25		0.96	3.85	2.78
Neshoba County General Hospital	48	34	17.13	35.68	4.14
Regency Hospital of Meridian	40		26.43	66.07	26.06
Rush Foundation Hospital	215		60.99	23.37	4.07
The Specialty Hospital of Meridian	49		43.66	89.10	27.35
Wayne General Hospital	80		18.13	22.66	4.01
General Hospital Service Area 7	579	16	140.39	24.25	3.39
Beacham Memorial Hospital	31	6	13.16	42.46	5.20
Field Health System	25		4.10	16.38	3.63
Franklin County Memorial Hospital	25	10	1.17	4.69	2.91
Jefferson County Hospital	30		3.32	11.06	10.41
King's Daughters Medical Center	99		28.20	28.48	2.57
Lawrence County Hospital	25		7.04	28.15	6.48
Merit Health Natchez	159		43.27	27.22	3.83
	1	1			
Southwest Mississippi Regional Medical Center	160		37.54	23.46	2.90

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Table 5-1 (continued)
Licensed Short-Term Acute Care Hospital Beds by Service Area
FY 2016

Facility	Licensed Beds	Abeyance Beds	Average Daily Census	Occupancy Rate	Average Length of Stay
General Hospital Service Area 8	1,180	41	513.90	43.55	4.62
Covington County Hospital	35		2.68	7.67	3.72
Forrest General Hospital	480		283.22	59.00	4.20
Greene County Hospital	7	3	0.58	8.22	2.76
Jasper General Hospital	16		0.06	0.39	4.60
Jefferson Davis General Hospital	35		5.05	14.43	7.39
Marion General Hospital	49	30	9.21	18.79	5.00
Merit Health Wesley	211		83.31	39.48	4.90
Perry County General Hospital	22	8	0.75	3.40	3.22
South Central Regional Medical Center	275		82.93	30.15	4.01
South Mississippi State Hospital	50		46.11	92.22	23.83
General Hospital Service Area 9	1,529	45	533.11	34.87	4.59
Garden Park Medical Center	130		42.13	32.41	4.31
George Regional Hospital	48		9.27	19.30	3.36
Hancock Medical Center	102		13.24	12.98	3.39
Highland Community Hospital	60	45	15.50	25.84	3.54
Memorial Hospital at Gulfport	348		185.85	53.41	4.88
Merit Health Biloxi	180		83.87	46.60	5.34
Ocean Springs Hospital	136		73.22	53.84	3.78
Pearl River County Hospital	24		0.20	0.83	2.92
Select Specialty Hospital - Gulf Coast	61		27.17	44.55	24.39
Singing River Hospital	415		79.24	19.09	3.98
Stone County Hospital	25		3.41	13.62	3.66
TOTAL	13,146	595	4,768.36	36.27	4.89

Notes: Occupancy rate is calculated based on total number of licensed beds and excludes beds in abeyance. As a result, the occupancy rate may not equal the occupancy rate published in the 2016 Mississippi Hospital Report.

Source: Application for Renewal of Hospital License for Calendar Year 2015 and FY 2016 Annual Hospital Report; Division of Health Planning and Resource Development, Office of Health Policy and Planning.

# 501 Hospital Outpatient Services

The following table shows the number of visits to hospital emergency rooms and hospital outpatient clinics in FY 2016. These statistics represent an increase over 2013's total of 4,877,339 visits to hospital emergency rooms and outpatient clinics.

Table 5-2
Selected Data for Hospital-Based or Affiliated Outpatient Clinics
by General Hospital Service Area
FY 2016

General	Number	Number of	Number of	Number of	
Hospital	with	Emergency	Hospitals with	Outpatient	Total
Service	Emergency	Room	Outpatient	Clinic	Outpatient
Area	Department	Visits	Clinics	Visits	Visits
Mississippi	84	1,931,303	76	3,698,269	5,629,572
1	5	132,004	5	74,383	206,387
2	8	203,360	7	357,607	560,967
3	7	147,798	4	248,158	395,956
4	13	219,362	12	511,299	730,661
5	19	481,425	20	1,029,974	1,511,399
6	6	114,467	7	285,068	399,535
7	8	113,616	7	208,541	322,157
8	8	190,306	6	186,975	377,281
9	10	328,965	8	796,264	1,125,229

Source: Applications for Renewals of Hospital License for Calendar Year 2015 and FY 2016 Annual Hospital Report, Mississippi State Department of Health.

#### 502 Certificate of Need Criteria and Standards for General Acute Care Facilities

Should MSDH receive a CON application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until MSDH has developed and adopted CON criteria and standards. If MSDH has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of MSDH.

# 502.01 Policy Statement Regarding Certificate of Need Applications for General Acute Care Hospitals and General Acute Care Beds

- 1. Need in Counties Without a Hospital: Ten counties in Mississippi do not have a hospital: Amite, Benton, Carroll, Humphreys, Issaquena, Itawamba, Prentiss Quitman, Smith and Tunica. Most of these counties do not have a sufficient population base to indicate a potential need for the establishment of a hospital, and all appear to receive sufficient inpatient acute care services from hospitals in adjoining counties.
- 2. <u>Expedited Review</u>: MSDH may consider an expedited review for CON applications that address only license code deficiencies, project cost overruns, and relocation of facilities or services.
- 3. <u>Capital Expenditure</u>: For the purposes of CON review, transactions which are separated in time but planned to be undertaken within twelve (12) months of each other and which are components of an overall long-range plan to meet patient care objectives shall be reviewed in their entirety without regard to their timing. For the purposes of this policy, the governing board of the facility must have duly adopted the long-range plan at least twelve (12) months prior to the submission of the CON application.
- 4. <u>Addition or Conversion of Beds</u>: No health care facility shall be authorized to add any beds or convert any beds to another category of beds without a CON.
- 5. Beds in Abeyance: If a health care facility has voluntarily delicensed some of its existing bed complement, it may later relicense some or all of its delicensed beds without the necessity of having to acquire a CON. MSDH shall maintain a record of the delicensing health care facility and its voluntarily delicensed beds and continue counting those beds as part of the state's total bed count for health care planning purposes.
- 6. <u>Break in Services</u>: A health care facility that has ceased to operate for a period of sixty (60) months or more shall require a CON prior to reopening.

# 502.02 Certificate of Need Criteria and Standards for the Establishment of a General Acute Care Hospital

MSDH will review applications for a CON to construct, develop, or otherwise establish a new hospital under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for a Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of MSDH; and the specific criteria and standards listed below.

#### **Need Criterion 1:** Acute Care Hospital Need Methodology

With the exception of psychiatric, chemical dependency, and rehabilitation hospitals, MSDH will use the following methodologies to project the need for general acute care hospitals:

#### a. Counties Without a Hospital

MSDH shall determine hospital need by multiplying the state's average annual occupied beds per 1,000 population (1.41 in FY 2013) by the estimated 2023 county population to determine the number of beds the population could utilize. A hospital with a maximum of 100 beds may be considered if the following three conditions are met: (i) the number of beds needed is 100 or more; (ii) there is strong community support for a hospital; and (iii) a hospital can be determined to be economically feasible.

## b. Counties With Existing Hospitals

MSDH shall use the following formula to determine the need for an additional hospital in a county with an existing hospital:

$$ADC + \frac{K}{ADC}$$

ADC = Average Daily Census K = Confidence Factor of 2.57

The formula is calculated for each facility within a given General Hospital Service Area (GHSA); then beds available and beds needed under the statistical application of the formula are totaled and subtracted to determine bed need or excess within each GHSA. Map 5-1 delineates the GHSAs. A hospital with a maximum of 100 beds may be considered if the following three conditions are met: (i) the number of beds needed is 100 or more; (ii) there is strong community support for a hospital; and (iii) a hospital can be determined to be economically feasible.

# c. Counties with Existing Hospitals Located in an Underdeveloped General Hospital Service Area and With a Rapidly Growing Population

If the need methodology in b above shows that a need does not exist in that county, an Applicant may further demonstrate need for an acute care hospital not to exceed one hundred (100) beds if the county has a population in excess of 140,000 people; the

county projects a population growth rate in excess of ten percent (10%) over the next ten (10) year period; and the county's GHSA does not presently exceed a factor of three beds per 1,000 population.

Further, any person proposing a new hospital under this criterion must meet the following conditions:

- i. Provide an amount of indigent care in excess of the average of the hospitals in the General Hospital Service Area as determined by the State Health Officer;
- ii. Provide an amount of Medicaid care in excess of the average of the hospitals in the General Hospital Service Area as determined by the State Health Officer; and
- iii. If the proposed hospital will be located in a county adjacent to a county or counties without a hospital, the applicant must establish outpatient services in the adjacent county or counties without a hospital;
- iv. Fully participate in the Trauma Care System at a level to be determined by the MSDH for a reasonable number of years to be determined by the State Health Officer. Fully participate means play in the Trauma Care System as provided in the Mississippi Trauma Care System Regulations and the new hospital shall not choose or elect to pay a fee not to participate or participate at a level lower than the level specified in the CON; and
- v. The new hospital must also participate as a network provider in the State and School Employees' Health Insurance Plan as defined in Mississippi Code Section 25-15-3 and 25-15-9.

#### **Need Criterion 2: Indigent/Charity Care**

The applicant shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care as described in Chapter 1 of this *Plan*.

# 502.03 Certificate of Need Criteria and Standards for Construction, Renovation, Expansion, Capital Improvements, Replacement of Health Care Facilities, and Addition of Hospital Beds

MSDH will review applications for a Certificate of Need for the addition of beds to a health care facility and projects for construction, renovation, expansion, or capital improvement involving a capital expenditure in excess of \$5,000,000 (for clinical health services) or \$10,000,000 (for nonclinical health services). MSDH will further review applications under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the MSDH; and the specific criteria and standards listed below.

The construction, development, or other establishment of a new health care facility, the replacement and/or relocation of a health care facility or portion thereof, and changes of ownership of existing health care facilities are reviewable regardless of capital expenditure.

#### **Need Criterion 1: Acute Care Bed Need**

#### a. Projects which do not involve the addition of any acute care beds

The applicant shall document the need for the proposed project. Documentation may consist of, but is not limited to, citing of licensure or regulatory code deficiencies, institutional long-term plans (duly adopted by the governing board), recommendations made by consultant firms, and deficiencies cited by accreditation agencies (JCAHO, CAP, etc.). In addition, for projects which involve construction, renovation, or expansion of emergency department facilities, the applicant shall include a statement indicating whether the hospital will participate in the statewide trauma system and describe the level of participation, if any.

#### b. Projects which involve the addition of beds

The applicant shall document the need for the proposed project. In addition to the documentation required as stated in Need Criterion (1) (a), the applicant shall document that the facility in question has maintained an occupancy rate of at least sixty percent (60%) for the most recent two (2) years or has maintained an occupancy rate of at least seventy percent (70%) for the most recent two (2) years according to the below formula:

# Observation patient days/365/ licensed beds + Inpatient Occupancy rate

Note: \*An observation patient day is a patient that has NOT been admitted as an inpatient, but occupies an acute care bed (observation bed) and is provided observation services in a licensed, acute care hospital. Hospitals shall follow strict guidelines set forth by The Centers for Medicare & Medicaid Services, health insurance companies, and others in reporting observation bed data to the Department. For definitions that correspond with the above referenced item, please refer to the Glossary included in the Plan.

#### Need Criterion 2: Bed Service Transfer/Reallocation/Relocation

Applications proposing the transfer, reallocation, and/or relocation of a specific category or sub-category of bed/service from another facility as part of a renovation, expansion, or replacement project shall document that the applicant will meet all regulatory/licensure requirements for the type of bed/service being transferred/reallocated/relocated.

#### **Need Criterion 3: Charity/Indigent Care**

The application shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care as described in Chapter 1 of this *Plan*.

#### **Need Criterion 4: Cost of Project**

The application shall demonstrate that the cost of the proposed project, including equipment, is reasonable in comparison with the cost of similar projects in the state.

a. The applicant shall document that the cost per square foot (per bed if applicable) does not exceed the median construction costs, as determined by the MSDH, for similar projects in the state within the most recent 12-month period by more than fifteen percent (15%). The Glossary of this *Plan* provides the formulas to be used by MSDH staff in calculating the cost per square foot for construction and/or construction/renovation projects.

b. If equipment costs for the project exceed the median costs for equipment of similar quality by more than fifteen percent (15%), the applicant shall provide justification for the excessive costs. The median costs shall be based on projects submitted during the most recent six-month period and/or estimated prices provided by acceptable vendors.

#### **Need Criterion 5: Project Specifications**

The applicant shall specify the floor areas and space requirements, including the following factors:

- a. The gross square footage of the proposed project in comparison to state and national norms for similar projects.
- b. The architectural design of the existing facility if it places restraints on the proposed project.
- c. Special considerations due to local conditions.

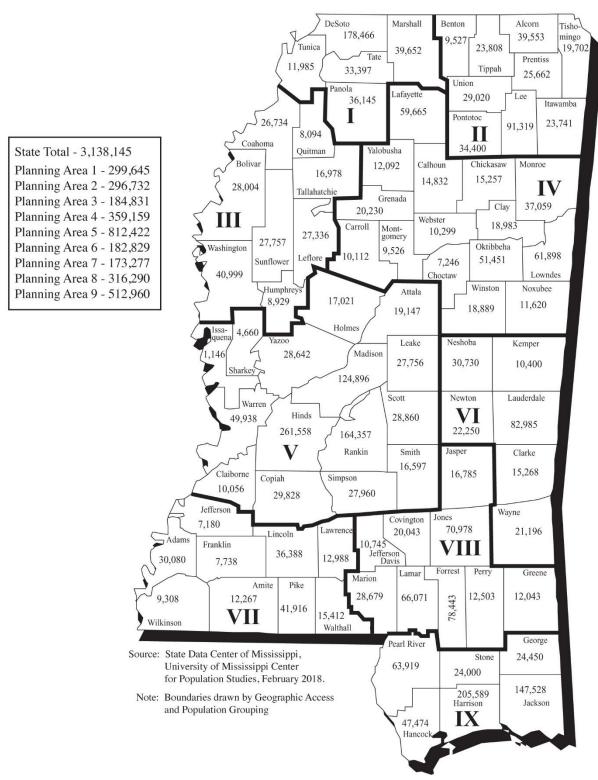
# **Need Criterion 6: Renovation/Expansion Justification**

If the cost of the proposed renovation or expansion project exceeds eighty-five percent (85%) of the cost of a replacement facility, the applicant shall document their justification for rejecting the option of replacing said facility.

#### **Need Criterion 7: Need for Service**

The applicant shall document the need for a specific service (i.e. perinatal, ambulatory care, psychiatric, etc.) using the appropriate service specific criteria as presented in this and other sections of the *Plan*.

Map 5-1 General Hospital Service Areas 2023 Population Projections



# 503 Long-Term Acute Care Hospitals

A long-term acute care (LTAC) hospital is a freestanding, Medicare-certified acute care hospital with an average length of inpatient stay greater than twenty-five (25) calendar days, which is primarily engaged in providing chronic or long-term medical care to patients who do not require more than three (3) hours of rehabilitation or comprehensive rehabilitation per day, and has a transfer agreement with an acute care medical center and a comprehensive medical rehabilitation facility. As of FY 2016, sixteen (16) long-term acute care hospitals were in operation. The following table lists specific LTAC information.

Table 5-3 Long-Term Acute Care Hospitals 2016

Facility	Location	Licensed Beds	Occupancy Rate	Dis charges	ALOS
General Hospital Service Are	a 1	0	0.00	0	0.00
NONE					
General Hospital Service Are	a 2	0	0.00	0	0.00
NONE					
General Hospital Service Are	a 3	79	53.20	737	20.91
Allegiance Specialty Hospital Greenville*	- Greenville	39	56.94	430	18.62
Greenwood AMG Specialty Hospital*	- Greenwood	40	49.55	307	24.12
General Hospital Service Are	a 4	0	0.00	0	0.00
NONE					
General Hospital Service Are	a 5	88	77.37	962	25.51
Mississippi Hospital for Restorative Care	- Jackson		0.00		0)
Promise Hospital of Vicksburg	- Vicksburg	35	79.48	377	25.84
Regency Hospital of Jackson	- Jackson		0.00		0.00
Select Specialty Hospital of Jackson	- Jackson	53	75.97	585	25.29
General Hospital Service Are	a 6	89	78.75	964	26.86
Regency Hospital of Meridian	- Meridian	40	66.07	370	26.06
Specialty Hospital of Meridian	- Meridian	49	89.10	594	27.35
General Hospital Service Are	a 7	0	0.00	0	0.00
NONE					
General Hospital Service Are	a 8	33	83.68	365	27.55
Regency Hospital of Southern Mississippi	- Hattiesburg	33	83.68	365	27.55
General Hospital Service Are	a 9	61	44.55	388	24.39
Select Specialty Hospital-Gulfport	- Gulfport	61	44.55	388	24.39
TOTAL		350	67.14	3,416	24.99

Note: There are currently no LTAC Hospitals located in GHSA 1, 2, 4, and 7.

Source: Applications for Renewal of Hospital License for Calendar Year 2016; FY 2017 Annual Hospital Report

## 504 Certificate of Need Criteria and Standards for Long-Term Acute Care Hospitals/Beds

Should MSDH receive a CON application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until MSDH has developed and adopted CON criteria and standards. If MSDH has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of MSDH.

# 504.01 Policy Statement Regarding Certificate of Need Applications for Long-Term Acute Care Hospitals and Long-Term Acute Care Hospital Beds

- 1. <u>Restorative Care Admissions:</u> Restorative care admissions shall be identified as patients with one or more of the following conditions or disabilities:
  - a. Neurological Disorders
    - i. Head Injury
    - ii. Spinal Cord Trauma
    - iii. Perinatal Central Nervous System Insult
    - iv. Neoplastic Compromise
    - v. Brain Stem Trauma
    - vi. Cerebral Vascular Accident
    - vii. Chemical Brain Injuries
  - b. Central Nervous System Disorders
    - Motor Neuron Diseases
    - ii. Post Polio Status
    - iii. Developmental Anomalies
    - iv. Neuromuscular Diseases (e.g. Multiple Sclerosis)
    - v. Phrenic Nerve Dysfunction

- vi. Amyotrophic Lateral Sclerosis
- c. Cardio-Pulmonary Disorders
  - i. Obstructive Diseases
  - ii. Adult Respiratory Distress Syndrome
  - iii. Congestive Heart Failure
  - iv. Respiratory Insufficiency
  - v. Respiratory Failure
  - vi. Restrictive Diseases
  - vii. Broncho-Pulmonary Dysplasia
  - viii.Post Myocardial Infarction
  - ix. Central Hypoventilation
- d. Pulmonary Cases
  - i. Presently Ventilator-Dependent/Weanable
  - ii. Totally Ventilator-Dependent/Not Weanable
  - iii. Requires assisted or partial ventilator support
  - iv. Tracheostomy that requires supplemental oxygen and bronchial hygiene
- 2. <u>Bed Licensure:</u> All beds designated as long-term care hospital beds shall be licensed as general acute care.
- 3. <u>Average Length of Stay:</u> Patients' average length of stay in a long-term care hospital must be twenty-five (25) calendar days or more.
- 4. <u>Size of Facility:</u> Establishment of a long-term care hospital shall not be for less than twenty (20) beds.

- 5. <u>Long-Term Medical Care:</u> A long-term acute care hospital shall provide chronic or long-term medical care to patients who do not require more than three (3) hours of rehabilitation or comprehensive rehabilitation per day.
- 6. <u>Transfer Agreement:</u> A long-term acute care hospital shall have a transfer agreement with an acute care medical center and a comprehensive medical rehabilitation facility.
- 7. Addition or Conversion of Beds: Effective July 1, 1994, no health care facility shall be authorized to add any beds or convert any beds to another category of beds without a CON under the authority of Section 41-7-191(1)(c), unless there is a projected need for such beds in the planning district in which the facility is located.

# 504.02 Certificate of Need Criteria and Standards for the Establishment of a Long-Term Acute Care Hospital and Addition of Long-Term Acute Care Hospital Beds

MSDH will review applications for a CON for the construction, development, or otherwise establishment of a long-term acute care hospital and bed additions under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for CON according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of MSDH; and the specific criteria and standards listed below.

#### **Need Criterion 1: Projected Need**

The applicant shall document a minimum of 450 clinically appropriate restorative care admissions with an average length of stay of twenty-five (25) days.

#### **Need Criterion 2: Financial Feasibility**

A projection of financial feasibility by the end of the third year of operation.

#### **Need Criterion 3: Bed Licensure**

The applicant shall document that any beds which are constructed/converted will be licensed as general acute care beds offering long-term acute care hospital services.

#### **Need Criterion 4: Licensure**

Applicants proposing the transfer/reallocation/relocation of a specific category or sub-category of bed/service from another facility as part of a renovation, expansion, or replacement project shall document that they will meet all regulatory and licensure requirements for the type of bed/service proposed for transfer/reallocation/relocation.

#### **Need Criterion 5: Indigent/Charity Care**

The application shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care as described in Chapter 1 of this *Plan*.

## **Need Criterion 6: Project Cost**

The application shall demonstrate that the cost of the proposed project, including equipment, is reasonable in comparison with the cost of similar projects in the state. The applicant shall document that the cost per square foot (per bed if applicable) does not exceed the median construction costs, as determined by the MSDH, for similar projects in the state within the most recent twelve (12) month period by more than fifteen percent (15%). The Glossary of this *Plan* provides the formulas MSDH staff shall use to calculate the cost per square foot of space for construction and/or construction-renovation projects.

## **Need Criterion 7: Floor Area and Space Requirements**

The applicant shall specify the floor areas and space requirements, including the following factors:

- a. The gross square footage of the proposed project in comparison to state and national norms for similar projects.
- b. The architectural design of the existing facility if it places restraints on the proposed project.
- c. Special considerations due to local conditions.

# **Need Criterion 8: Transfer Agreement**

The applicant shall provide copies of transfer agreements entered into with an acute care medical center and a comprehensive medical rehabilitation facility.

# 505 Swing -Bed Programs and Extended Care Services

Federal law allows rural hospitals with fewer than 100 hospital beds to utilize its beds as "swing beds" to provide post-acute extended care services. 42 C.F.R. § 482.58. Hospitals must have a Medicare provider agreement and meet several eligibility and skilled nursing facility service requirements to be granted CMS approval to provide post-hospital extended care services and to be reimbursed as a swing-bed hospital.

Swing-bed hospitals have the same Medicare coverage requirements and coinsurance provisions as nursing facilities. In addition to meeting acute care standards, swing-bed hospitals must also substantially comply with the eight skilled nursing facility services standards listed in 42 C.F.R. §482.58(b). These standards include resident rights, admission, transfer, and discharge rights, freedom from abuse, neglect, and exploitation, dental services, specialized rehabilitative services, social services, patient activities, and discharge planning. Because many patients, particularly elderly patients, no longer need acute hospital care but are not well enough to go home, swing-beds enable the hospital to provide nursing care, rehabilitation, and social services with a goal of returning patients to their homes. Many of these patients would become nursing home residents without the extended period of care received in a swing-bed.

Swing-beds provide a link between inpatient acute care and home or community-based services in a continuum for the elderly and others with long-term needs. If it is not possible for the patient to return home, the swing-bed hospital assists the patient and their family with nursing home placement. Ideally, the swing-bed concept should help alleviate low utilization problems in small rural hospitals and provide a new revenue source with few additional expenses while also more efficiently utilizing hospital staff during periods of low acute care occupancy.

#### 505.01 Swing -Bed Utilization

Forty-seven (47) Mississippi hospitals and one specialty hospital participated in the swing bed program during Fiscal Year 2016. They reported 6,980 discharges from their swing beds and an average length of stay of 16.25 days.

Table 5-4 Swing-Bed Utilization FY 2016

	T:			A
TO . 114	Licensed	D'	AT OG	Average
Facility	Beds	Discharges	ALOS	Daily Census
General Hospital Service Area 1	3	33	6.79	0.57
Alliance Health Care System	3	33	6.79	0.57
General Hospital Service Area 2	35	1047	13.97	43.84
Baptist Memorial Hospital-Union County	0	95	7.73	1.98
Laird Hospital	25	247	11.35	7.71
Pontotoc Health Services	0	343	20.22	19.29
Tippah County Hospital	10	166	16.18	7.16
Tishomingo Health Services, Inc.	10	196	14.35	7.70
General Hospital Service Area 3	66	615	28.90	23.51
Bolivar Medical Center	12	127	10.21	3.65
North Sunflower Medical Center	15	322	14.07	12.96
South Sunflower County Hospital	30	107	15.69	4.63
Tallahatchie General Hospital	9	59	75.61	2.27
General Hospital Service Area 4	151	1,782	14.65	71.71
Baptist Memorial Hospital- Calhoun	25	100	23.82	6.27
Choctaw Regional Medical Center	15	149	13.62	5.37
Clay County Medical Corporation	10	196	11.56	6.20
Gilmore Memorial Hospital	0	59	6.63	1.07
Monroe Regional Hospital	0	245	15.76	10.37
Noxubee General Critical Access Hospital	25	173	16.11	7.74
Oktibbeha County Hospital	10	124	8.79	3.06
Trace Regional Hospital	10	4	22.25	0.28
Tyler Holmes Memorial Hospital	10	140	17.15	6.87
Webster Health Services	20	349	13.50	12.81
Winston Medical Center	0	13	8.46	0.30
Yalobusha General Hospital	26	230	18.15	11.37
General Hospital Service Area 5	54	1,063	15.00	54.08
Baptist Medical Center- Attala, Inc.	0	0	0.00	7.82
Baptist Medical Center - Yazoo, Inc.	10	185	14.17	5.06
Baptist Medical Center- Leake, Inc.	25	281	17.07	12.69
Holmes County Hospital & Clinics	0	69	18.86	4.09
Magee General Hospital	12	158	17.52	7.72
Claiborne County Hospital	7	126	14.41	5.02
Scott Regional Hospital	0	83	23.43	5.14
Simpson General Hospital	0	161	14.56	6.54

Source: Applications for Renewal of Hospital License for Calendar Year 2016; FY 2017 Annual Hospital Report

Table 5-4 (Continued) Swing-Bed Utilization FY 2016

	Licensed			Average
Facility	Beds	Discharges	ALOS	Daily Census
General Hospital Service Area 6	115	1,018	11.51	40.86
Anderson Regional Medical Center South	25	362	16.45	16.31
H.C. Watkins Memorial Hospital	25	207	16.11	8.98
John C Stennis Memorial Hospital	25	217	11.83	7.13
Neshoba County General Hospital	10	25	11.44	0.79
Speciality Hospital of Meridan	20	0	0	0.01
Wayne General Hospital	10	207	13.20	7.64
General Hospital Service Area 7	51	518	18.82	28.50
Field Health System	16	125	16.53	5.55
Franklin County Memorial Hospital	25	194	28.21	14.79
Lawerence County Hospital	10	95	16.08	4.22
Walthall County General Hospital	0	104	14.45	3.94
General Hospital Service Area 8	57	720	17.80	34.75
Covington County Hospital	25	248	15.66	10.44
Greene County Hospital	0	75	19.80	4.07
Jasper General Hospital	12	127	20.57	6.99
Jefferson Davis Community Hospital	0	66	13.61	2.50
Marion General Hospital	20	204	19.34	10.75
Ganeral Hospital Service Area 9	0	184	18.77	13.72
George Regional Hospital	0	7	10.43	0.20
Stone County Hospital	0	177	27.11	13.52
State Total	532	6,980	16.25	311.54

Source: Applications for Renewal of Hospital License for Calendar Year 2016; FY 2017 Annual Hospital Report

Note(s): According to the Applications for Renewal of Hospital License for Calendar Year 2016 and FY 2017 Annual Hospital Report: Baptist Memorial Hospital-Union County, Pontotoc Health Services, Gilmore Memorial Hospital, Monroe Regional Hospital, Winston Medical Center, Baptist Medical Center- Attala, Inc., Holmes County Hospital & Clinics, Scott Regional Hospital, Simpson General Hospital and George Regional Hospital reported zero (0) licensed Swing Beds.

#### 505.02 Certificate of Need Criteria and Standards for Swing-Bed Services

MSDH will review applications for a CON to establish swing-bed services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for CON according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the MSDH; and the specific criteria and standards listed below.

#### **Need Criterion 1: Federal Requirements**

The application shall document that the hospital will meet all federal regulations regarding the swing-bed concept. However, a hospital may have more licensed beds or a higher average daily census (ADC) than the maximum number specified in federal regulations for participation in the swing-bed program.

#### **Need Criterion 2: Resolution Adopted for Proposed Participation**

The applicant shall provide a copy of the Resolution adopted by its governing board approving the proposed participation.

Need Criterion 3: Hospitals Proposing Beds over the Maximum allowed by Federal Law If the applicant proposes to operate and staff more than the maximum number of beds specified in federal regulations for participation in the swing-bed program, the application shall give written assurance that only private pay patients will receive swing-bed services once the federal threshold is met.

#### **Need Criterion 4: Medicare Recipients**

The application shall affirm that upon receiving CON approval and meeting all federal requirements for participation in the swing-bed program, the applicant shall render services provided under the swing-bed concept to any patient eligible for Medicare (Title XVIII of the Social Security Act) who is certified by a physician to need such services.

#### **Need Criterion 5: Limitation on Medicare/Medicaid Patients**

The application shall affirm that upon receiving CON approval and meeting all federal requirements for participation in the swing-bed program, the applicant shall not permit any patient who is eligible for both Medicaid and Medicare or is eligible only for Medicaid to stay in the swing-beds of a hospital for more than thirty (30) days per admission unless the hospital receives prior approval for such patient from the Division of Medicaid.

# Need Criterion 6: Hospitals with More Licensed Beds or a Higher Average Daily Census

The application shall affirm that if the hospital has more licensed beds or a higher average daily census than the maximum number specified in federal regulations for participation in the swing-bed program, the applicant will develop a procedure to ensure that, before a patient is allowed to stay in the swing-beds of the hospital, there are no vacant nursing home beds available within a fifty (50) mile radius (geographic area) of the hospital. The applicant shall also affirm that if the hospital has a patient staying in the swing-beds of the hospital and the hospital receives notice from a nursing home located within a fifty (50) mile radius that there

is a vacant bed available for that patient, the hospital shall transfer the swing-bed patient to the nursing home within five days, exclusive of holidays and weekends, unless the patient's physician certifies that the transfer is not medically appropriate.

#### **Need Criterion 7: Transfer Agreements**

The applicant shall provide copies of transfer agreements entered into with each nursing facility within the applicant's geographic area.

#### **Need Criterion 8: Failure to Comply**

An applicant subject to the conditions stated in Need Criterion #5 shall affirm in the application that they will be subject to suspension from participation in the swing-bed program for a reasonable period of time by MSDH, after a hearing complying with due process, MSDH, determines that the hospital has failed to comply with any of those requirements.

## 506 Therapeutic Radiation Services

Therapeutic radiology (also called radiation oncology, megavoltage radiotherapy, or radiation therapy) is the treatment of cancer and other diseases with radiation. Radiation therapy uses high energy photons (x-ray or gamma rays) or charged particles (electrons, protons or heavy nuclei) to damage critical biological molecules in tumor cells. Radiation in various forms is used to kill cancer cells by preventing them from multiplying. Therapeutic radiation may be used to cure or control cancer, or to alleviate some of the symptoms associated with cancer (palliative care). Radiation therapy services does not include low energy, superficial, external beam x-ray treatment of superficial skin lesions.

In radiation therapy, a non-invasive treatment can be given repetitively over several weeks to months and can be aimed specifically at the area where treatment is needed, minimizing side effects for uninvolved normal tissues. This repetitive treatment is called fractionation because a small fraction of the total dose is given each treatment. Radiotherapy can only be performed with linear accelerator (linac) technology. Conventionally administrated external beam radiation therapy gives a uniform dose of radiation to the entire region of the body affected by the tumor. Only a small variation of the dose is delivered to various parts of the tumor. Radiotherapy may not be as effective as stereotactic radiosurgery, which can give higher doses of radiation to the tumor itself.

Another type of radiation therapy used in Mississippi is brachytherapy. Unlike the external beam therapy, in which high-energy beams are generated by a machine and directed at a tumor from outside the body, brachytherapy involves placing a radioactive material directly into the body.

## 507 Stereotactic Radiosurgery

Despite its name, stereotactic radiosurgery is a non-surgical procedure that uses highly focused x-rays (or in some cases, gamma rays) to treat certain types of tumors, inoperable lesions, and as a post-operative treatment to eliminate any leftover tumor tissue. Stereotactic radiosurgery treatment involves the delivery of a single high-dose — or in some cases, smaller multiple doses — of radiation beams that converge on the specific area of the brain where the tumor or other abnormality resides.

Stereotactic radiosurgery was once limited to the GammaKnife® for treating intra-cranial lesions and functional issues. With the introduction of CyberKnife® and other LINAC-based radiosurgery systems, there has been rapid growth in total-body radiosurgery. The modified LINAC radiosurgery modality is now being used to treat lung, liver, pancreas, prostate, and other body areas. Some modified full-body LINAC models use full-body frames as a guiding tool and others do not. Therefore, the term "stereotactic radiosurgery" will refer to radiosurgery regardless of whether a full-body frame is used or not. A full course of radiosurgery requires only one to five (5) treatments versus thirty (30) to forty (40) for radiotherapy.

Three (3) basic types of stereotactic radiosurgery are in common use, each of which uses different instruments and sources of radiation:

**Cobalt 60 Based (Gamma Knife),** which uses 201 beams of highly focused gamma rays. Because of its incredible accuracy, the Gamma Knife is ideal for treating small to medium size lesions.

**Linear accelerator (LINAC) based** machines, prevalent throughout the world, deliver high-energy x-ray photons or electrons in curving paths around the patient's head. The linear accelerator can perform radiosurgery on larger tumors in a single session or during multiple sessions (fractionated stereotactic radiotherapy). Multiple manufacturers make linear accelerator machines, which have names such as:

Axess®, Clinac®, Cyberknife®, Novalis®, Peacock®, TomoTherapy®, Trilogy®, or X-Knife®. According to Accuray, the CyberKnife® is the world's only robotic radiosurgery system designed to treat tumors anywhere in the body non-invasively and with sub-millimeter accuracy.

Particle beam (photon) or cyclotron based machines are in limited use in North America.

Table 5-5 presents the facilities offering megavoltage therapeutic radiation therapy.

# 508 Diagnostic Imaging Services

Diagnostic imaging equipment and services, except for magnetic resonance imaging, positron emission tomography, and invasive digital angiography, are reviewable under the state's Certificate of Need law only when the capital expenditure for the acquisition of the equipment and related costs exceeds \$1.5 million. The provision of invasive diagnostic imaging services, i.e., invasive digital angiography, positron emission tomography, and the provision of magnetic resonance imaging services require a Certificate of Need if the proposed provider has not offered the services on a regular basis within 12 months prior to the time the services would be offered, regardless of the capital expenditure.

Equipment in this category includes, but is not limited to: ultrasound, diagnostic nuclear medicine, digital radiography, angiography equipment, computed tomographic scanning equipment, magnetic resonance imaging equipment, and positron emission tomography.

Table 5-5
Facilities Reporting Megavoltage Therapeutic Radiation Services
by General Hospital Service Area
FY 2015 and FY 2016

Facility	County	Number of Treatments (Visits)			
		2015	2016		
General Hospital Service Area 1		10,302	9,875		
Baptist Memorial Hospital - DeSoto	DeSoto	10,302	9,875		
General Hospital Service Area 2		17,196	14,438		
Magnolia Regional Health Center	Alcorn	4,003	3,873		
North Miss Medical Center	Lee	13,193	10,565		
General Hospital Service Area 3		9,043	10,550		
Alliance Cancer Center-Clarksdale	Coahoma	2,237	2,130		
Alliance Cancer Center- Greenville	Washington	3,589	4,058		
Greenwood Leflore Hospital	Leflore	3,217	4,362		
General Hospital Service Area 4		24,033	22,540		
Baptist Memorial Hospital - Golden Triangle	Lowndes	18,152	15,625		
Baptist Memorial Hospital - North Miss	Lafayette	5,881	6,915		
Cancer Care at Premier Health Complex <sup>1</sup>	Oktibbeha	DNS	DNS		
General Hospital Service Area 5		47,484	44,916		
Vicksburg Oncology Associates <sup>1</sup>	Warren	4,492	4,653		
Merit Health Central	Hinds	7,542	6,002		
Miss Baptist Medical Center	Hinds	11,561	11,472		
Promise Hospital of Vicksburg	Warren	-	-		
St. Dominic Jackson- Memorial Hospital	Hinds	12,937	12,015		
University of Mississippi Medical Center	Hinds	10,952	10,774		
General Hospital Service Area 6		1	1		
Anderson Regional Cancer Center	Lauderdale	1	1		
General Hospital Service Area 7		7,480	7,597		
Caring River Cancer Center <sup>1</sup>	Adams	2,814	3,130		
Southwest Miss Regional Medical Center	Pike	4,666	4,467		
General Hospital Service Area 8		19,577	21,312		
Forrest General Hospital	Forrest	15,580	17,281		
Laurel Cancer Care <sup>1</sup>	Jones	3,997	3,942		
Regency Hospital of Hattiesburg*	Forrest	-	-		
South Central Regional Medical Center****	Jones	-	89		
General Hospital Service Area 9		18,968	52,349		
Cedar Lake Oncology Center <sup>1</sup>	Harrison	2,439	3,915		
Memorial Hospital at Gulfport	Harrison	9,586	10,611		
Merit Health Biloxi	Harrison	2,436	33,316		
Ocean Springs Hospital**	Jackson	-	-		
Select Specialty Hospital - Gulf Coast***	Harrison	-   -			
Singing River Hospital**	Jackson	4,507	4,507		
State Total		154,084	183,578		

<sup>&</sup>lt;sup>1</sup> Indicates freestanding clinics.

DNS- Did Not Submit

Sources: Applications for Renewal of Hospital License for Calendar Years 2015 and 2016

<sup>\*</sup>Regency Hospital of Hattiesburg uses Forrest General Hospital's Linear Accelerator Machine.

<sup>\*\*</sup>Singing River Hospital and Ocean Springs Hospital share one Linear Accelerator Machine.

<sup>\*\*\*</sup>Select Specialty Hospital – Gulf Coast uses Memorial Hospital at Gulfport's Linear Accelerator Machine.

<sup>\*\*\*\*</sup>South Central Regional Medical Center uses Laurel Cancer Care's Linear Accelerator Machine.

# 509 Certificate of Need Criteria and Standards for Therapeutic Radiation Services

**Note:** Should MSDH receive a CON application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until MSDH has developed and adopted CON criteria and standards. If MSDH has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of MSDH.

# 509.01 Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Therapeutic Radiation Equipment, and/or the Offering of Therapeutic Radiation Services (other than Stereotactic Radiosurgery)

- 1. <u>Service Areas</u>: MSDH shall determine the need for therapeutic radiation services equipment using the General Hospital Service Areas as presented in this chapter of the *Plan*. MSDH shall determine the need for therapeutic radiation services and equipment within a given service area independently of all other service areas. Map 5-1 shows the General Hospital Service Areas.
- 2. Equipment to Population Ratio: The need for therapeutic radiation units (as defined) is determined to be one unit per 142,592 population (see methodology in Section 509.02.02 of the *Plan*). MSDH will consider out-of-state population in determining need only when the applicant submits adequate documentation acceptable to MSDH, such as valid patient origin studies.
- 3. <u>Limitation of New Services</u>: When the therapeutic radiation unit-to-population ratio reaches one to 142,592 in a given general hospital service area, no new therapeutic radiation services may be approved unless the utilization of all the existing machines in a given hospital service area averaged 8,000 treatments or 320 patients per year for the two most recent consecutive years as reported on the "Renewal of Hospital License and Annual Hospital Report." For purposes of this policy Cesium-137 teletherapy units, Cobalt-60 teletherapy units designed for use at less than 80 cm SSD (source to skin distance), old betatrons and van de Graaf Generators, unsuitable for modern clinical use, shall not be counted in the inventory of therapeutic radiation units located in a hospital service area.
- 4. Expansion of Existing Services: MSDH may consider a CON application for the acquisition or otherwise control of an additional therapeutic radiation unit by an existing provider of such services when the applicant's existing equipment has exceeded the expected level of patient service, i.e., 320 patients per year or 8,000 treatments per year for the two most recent consecutive years as reported on the facility's "Renewal of Hospital License and Annual Hospital Report."
- 5. Equipment Designated for Backup: Therapeutic radiation equipment designated by an applicant as "backup" equipment shall not be counted in the inventory for CON purposes. Any treatments performed on the "backup" equipment shall be attributed to the primary equipment for CON purposes. "Backup" equipment should only be utilized when the primary equipment is deemed out of service.

- 6. <u>Definition of a Treatment</u>: For health planning and CON purposes a patient "treatment" is defined as one individual receiving radiation therapy during a visit to a facility which provides megavoltage radiation therapy regardless of the complexity of the treatment or the number of "fields" treated during the visit.
- 7. <u>Use of Equipment or Provision of Service</u>: Before the equipment or service can be utilized or provided, the applicant desiring to provide the therapeutic radiation equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval, as determined MSDH through a determination of non-reviewability.

# 509.02 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Therapeutic Radiation Equipment and/or the Offering of Therapeutic Radiation Services (other than Stereotactic Radiosurgery)

MSDH will review CON applications for the acquisition or otherwise control of therapeutic radiation equipment and/or the offering of therapeutic radiation services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for CON according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of MSDH; and the specific criteria and standards listed below.

The acquisition or otherwise control of therapeutic radiation equipment is reviewable if the equipment cost exceeds \$1,500,000. The offering of therapeutic radiation services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered, regardless of the capital expenditure.

## **Need Criterion 1: Project Need**

The applicant shall document a need for therapeutic radiation equipment/service by complying with any one of the following methodologies:

- a. the need methodology as presented in this section of the *Plan*;
- b. demonstrating that all existing machines in the service area in question have averaged 8,000 treatments per year or all machines have treated an average of 320 patients per year for the two most recent consecutive years; or
- c. demonstrating that the applicant's existing therapeutic equipment has exceeded the expected level of patients service, i.e., 320 patients per year/unit, or 8,000 treatments per year/unit for the most recent 24-month period.

#### **Need Criterion 2: Presence of Readily Available Services**

The applicant must document that access to diagnostic X-ray, CT scan, and ultrasound services is readily available within fifteen (15) minutes normal driving time of the therapeutic radiation unit's location.

# **Need Criterion 3: Staffing Requirements**

An applicant shall document the following:

- a. The service will have, at a minimum, the following full-time dedicated staff:
  - i. One board-certified radiation oncologist-in-chief
  - ii. One dosimetrist
  - iii. One certified radiation therapy technologist certified by the American Registry of Radiation Technologists
  - iv. One registered nurse
- b. The service will have, at a minimum, access to a radiation physicist certified or eligible for certification by the American Board of Radiology.

**Note**: One individual may act in several capacities. However, the application shall affirm that when a staff person acts in more than one capacity, that staff person shall meet, at a minimum, the requirements for each of the positions they fill.

#### **Need Criterion 4: Access to Additional Staff**

The applicant shall affirm that access will be available as needed to brachytherapy staff, treatment aides, social workers, dietitians, and physical therapists.

#### **Need Criterion 5: Physician Location**

Applicants shall document that all physicians who are responsible for therapeutic radiation services in a facility, including the radiation oncologist-in-chief, shall reside within sixty (60) minutes normal driving time of the facility.

#### Need Criterion 6: Access to a Modern Stimulator

The application shall affirm that the applicant will have access to a modern simulator capable of precisely producing the geometric relationships of the treatment equipment to a patient. This simulator must produce high quality diagnostic radiographs. The applicant shall also affirm that the following conditions will be met as regarding the use of the simulator:

- a. If the simulator is located at a site other than where the therapeutic radiation equipment is located, protocols will be established which will guarantee that the radiation oncologist who performs the patient's simulation will also be the same radiation oncologist who performs the treatments on the patient.
- b. If the simulator uses fluoroscopy, protocols will be established to ensure that the personnel performing the fluoroscopy have received appropriate training in the required techniques related to simulation procedures.

**Note**: X-rays produced by diagnostic X-ray equipment and photon beams produced by megavoltage therapy units are unsuitable for precise imaging of anatomic structures within the treatment volume and do not adequately substitute for a simulator.

## Need Criterion 7: Access to Computerized Treatment Planning System

The application shall affirm that the applicant will have access to a computerized treatment planning system with the capability of simulation of multiple external beams, display isodose distributions in more than one plane, and perform dose calculations for brachytherapy implants.

**Note**: It is highly desirable that the system have the capability of performing CT based treatment planning.

#### **Need Criterion 8: Supervision of Treatment**

The applicant shall affirm that all treatments will be under the control of a board certified or board eligible radiation oncologist.

## Need Criterion 9: MSDH Division of Radiological Health Approval

The applicant shall affirm that the proposed site, plans, and equipment shall receive approval from the MSDH Division of Radiological Health before service begins.

# **Need Criterion 10: Quality Assurance Program**

The application shall affirm that the applicant will establish a quality assurance program for the service, as follows:

- a. The therapeutic radiation program shall meet, at a minimum, the physical aspects of quality assurance guidelines established by the American College of Radiology (ACR) within 12 months of initiation of the service.
- b. The service shall establish a quality assurance program which meets, at a minimum, the standards established by the American College of Radiology.

# **Need Criterion 11: Failure to Comply**

The applicant shall affirm understanding and agreement that failure to comply with\_Need Criterion#10 (a) and (b) may result in revocation of the CON (after due process) and subsequent termination of authority to provide therapeutic radiation services.

#### 509.02.01 Therapeutic Radiation Equipment/Service Need Methodology

- 1. <u>Treatment/Patient Load</u>: A realistic treatment/patient load for a therapeutic radiation unit is 8,000 treatments or 320 patients per year.
- 2. <u>Incidence of Cancer</u>: The American Cancer Society (ACS) estimates that Mississippi will experience 8,130 new cancer cases in 2018. Based on a population of 3,138,145 (year 2023) as estimated by the State Data Center of Mississippi (University of Mississippi Center for Population Studies) is 2.59 cases per 1,000 population.
- 3. <u>Patients to Receive Treatment</u>: The number of cancer patients expected to receive therapeutic radiation treatment is set at forty-five percent (45%).
- 4. <u>Population to Equipment Ratio</u>: Using the above stated data, a population of 100,000 will generate 259 new cancer cases each year. Assuming that forty-five percent (45%) will receive radiation therapy, a population of 274,560 will generate approximately 320 patients

who will require radiation therapy. Therefore, a population of 274,560 will generate a need for one therapeutic radiation unit.

# 509.02.02 Therapeutic Radiation Equipment Need Determination Formula

1. Project annual number of cancer patients:

General Hospital Service 2.59 cases\*

Area Population X = 1,000 population = New Cancer Cases

\*Mississippi cancer incidence rate

2. Project the annual number of radiation therapy patients:

New Cancer Cases X 45% = Patients Who Will Likely Require Radiation Therapy

3. Estimate number of treatments to be performed annually:

Radiation Therapy Patients X 25 Treatments per Patient (Avg.) = Estimated Number of Treatments

4. Project number of megavoltage radiation therapy units needed:

<u>Est. # of Treatments</u> = Projected Number of Units Needed 8,000 Treatments per Unit

5. Determine unmet need (if any):

Projected Number of Units Needed — Number of Existing Units = Number of Units Required (Excess)

# 509.03 Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Stereotactic Radiosurgery Equipment, and/or the Offering of Stereotactic Radiosurgery

- 1. <u>Service Areas</u>: MSDH shall determine the need for stereotactic radiosurgery services and equipment by using the actual stereotactic radiosurgery provider's service area.
- 2. <u>Unit-to Population Ratio</u>: The need for stereotactic radiosurgery units is determined to be the same as for radiotherapy, for 2023 a population of 3,138,145. The therapeutic radiation need determination formula is outlined in Section 509.02.02 above.
- 3. Accessibility: Nothing contained in these CON criteria and standards shall preclude the University Of Mississippi School Of Medicine from acquiring and operating stereotactic radiosurgery equipment, provided the acquisition and use of such equipment is justified by the School's teaching and/or research mission and complies with the teaching exception as outlined in Section 102.01 of this Plan. However, the requirements listed under the section regarding the granting of "appropriate scope of privileges for access to the stereotactic radiosurgery equipment to any qualified physician" must be met.

- 4. Expansion of Existing Services: MSDH may consider a CON application for the acquisition or otherwise control of an additional stereotactic radiosurgery unit by an existing provider of such services when the applicant's existing equipment has exceeded the expected level of patient service, i.e., 900 treatments per year for the two most recent consecutive years as reported on the facility's "Renewal of Hospital License and Annual Hospital Report."
- 5. <u>Addition of Services:</u> Facilities requesting approval to add stereotactic radiosurgery services should have an established neurosurgery program and must be able to demonstrate previous radiosurgery service experience.
- 6. <u>Discharge Planning Policy</u>: All stereotactic radiosurgery services should have written procedures and policies for discharge planning and follow-up care for the patient and family as part of the institution's overall discharge planning program.
- 7. <u>Referral Policy</u>: All stereotactic radiosurgery services should have established protocols for referring physicians to assure adequate post-operative diagnostic evaluation for radiosurgery patients.
- 8. <u>Service Cost Comparison</u>: The total cost of providing stereotactic radiosurgery services projected by prospective providers should be comparable to the cost of other similar services provided in the state.
- 9. <u>Patient Cost Comparison</u>: The usual and customary charge to the patient for stereotactic radiosurgery should be commensurate with cost.

# 509.04 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Stereotactic Radiosurgery Equipment and/or the Offering of Stereotactic Radiosurgery

MSDH will review CON applications for the acquisition or otherwise control of stereotactic radiosurgery equipment and/or the offering of stereotactic radiosurgery services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of MSDH; and the specific criteria and standards listed below.

The acquisition or otherwise control of stereotactic radiosurgery equipment is reviewable if the equipment cost exceeds \$1,500,000. The offering of stereotactic radiosurgery services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered, regardless of the capital expenditure.

#### **Need Criterion 1: Minimum Procedures**

The applicant shall document a need for stereotactic radiosurgery equipment/service by reasonably projecting that the proposed new service will perform at least 900 stereotactic radiosurgery treatments in the third year of operation. No additional new stereotactic

radiosurgery services should be approved unless the number of stereotactic radiosurgery treatments performed with existing units in the state average 900 treatments or more per year.

#### **Need Criterion 2: Staffing Requirements**

- a. The radiosurgery programs must be established under the medical direction of two codirectors, one with specialty training and board certification in neurosurgery and the other with specialty training and board certification in radiation oncology, with experience in all phases of stereotactic radiosurgery.
- b. In addition to the medical co-directors, all stereotactic radiosurgery programs should have a radiation physicist who is certified in radiology, or who holds an advanced degree in physics with two to three years experience working under the direction of a radiation oncologist, and a registered nurse present for each stereotactic radiosurgery performed.
- c. The applicant shall document that the governing body of the entity offering stereotactic radiosurgery services will grant an appropriate scope of privileges for access to the stereotactic radiosurgery equipment to any qualified physician who applies for privileges. For the purpose of this criterion, "Qualified Physician" means a doctor of medicine or osteopathic medicine licensed by the State of Mississippi who possesses training in stereotactic radiosurgery and other qualifications established by the governing body.

## **Need Criterion 3: Equipment**

- Facilities providing stereotactic radiosurgery services should have dosimetry and calibration equipment and a computer with the appropriate software for performing stereotactic radiosurgery.
- b. The facility providing stereotactic radiosurgery services should also have access to magnetic resonance imaging, computed tomography, and angiography services.

# 510 Computed Tomographic (CT) Scanning

Should the capital expenditure for the acquisition of fixed or mobile CT scanning services, equipment, and related costs exceed \$1.5 million, the CON proposal will be reviewed under the general review criteria outlined in the most recent Certificate of Need Review Manual adopted by the Mississippi State Department of Health and the following utilization standards:

- A proposed unit must be able to generate a minimum of 2,000 HECTs (See Table 5-6 for HECT conversion table) by the second year of operation.
- Providers desiring CT capability must be properly utilizing 20,000 general radiographic imaging procedures per year.

#### 510.01 Magnetic Resonance Imaging (MRI)

Magnetic resonance imaging (MRI) is a diagnostic imaging technique that employs magnetic and radio-frequency fields to produce images of the body non-invasively. Magnetic resonance imaging is similar to CT scanning in that it produces cross-sectional and digital images without potentially harmful ionizing radiation, producing an image not distorted by bone mass. The equipment and its operational specifications continue to be refined.

Sixty-four (64) facilities (hospitals and free-standing) in Mississippi operated fixed or mobile based MRI units in FY 2016. These facilities performed a total of data to be inserted] MRI procedures during the year. Table 5-6 presents the location, type (fixed or mobile and number of units per facility), and utilization of MRI equipment throughout the state in fiscal years 2015 and 2016.

Table 5-6 Location and Number of MRI Procedures by General Hospital Service Area FY 2015 and FY 2016

	Type of Providers	County	Type of	Number Proce		Days/Hours of Operation
	Providers		Equipment	2015	2016	2016
General Hospital S	Service Area			13,436	13,416	
Baptist Memorial Hospital - DeSoto	Н	DeSoto	F(3)	8,022	7,502	M-Sun.72 Hrs.
Desoto Imaging Specialists	FS	DeSoto	F	3,366	3,060	M-F, 60 Hrs.
Methodist Healthcare Olive Branch Hospital	Н	DeSoto	F	1,394	2,106	M-F, 40 Hrs.
Panola Medcial Center	Н	Panola	M	654	748	M, Th, F 25 Hrs.
Superior MRI Services	MP	Panola	M	-	-	N/A
General Hospital S	Service Area 2	2		29,868	31,182	
Baptist Memorial Hospital - Booneville	Н	Prentiss	F	817	725	M-F, 40 Hrs
Baptist Memorial Hospital - Union	Н	Union	F M(4)	2,353	2,831	Mon-Sat., 168 Hrs.
Imaging Center of Gloster Creek Village ****	FS	Lee	F			M-F,40 Hrs.
Magnolia Regional Health Center	Н	Alcorn	F(2)	6,727	6,311	M-F- 40 Hrs.
Medical Imaging at Barnes Crossing	FS	Lee	F	3,664	3,595	M-F, 40 Hrs.
Medical Imaging at Crossover Road	FS	Lee	F	2,249	2,614	M-F, 40 Hrs.
North Miss. Medical Center	Н	Lee	F(4)	13,217	14,327	M-F, 240 Hrs.
Tishomingo Health Services, Inc.	Н	Tishomingo	M	841	779	M-F, 40 Hrs.
General Hospital S	Service Area	3		10,398	10,738	
Allegiance Specialty House of Greenville	Н	Washington	F	61	62	M-F. 40 Hrs.
Bolivar Medical Center	Н	Bolivar	M	1,038	1,208	M-F, 40 Hrs.
Delta Regional Med. Center-Main Campus	Н	Washington	F	2,548	2,497	M-F, 40 Hrs.
Greenwood Leflore Hospital	Н	Leflore	F	3,366	3,479	M-F, 50+ Hrs.
North Sunflower Medical Center	Н	Sunflower	F	706	645	Tu, Th. 8 Hrs.
Northwest Miss. Regional Medical Center	Н	Coahoma	F	1,509	1,601	M-F, 40 Hrs.
South Sunflower County Hospital	Н	Sunflower	M	441	369	W., 4 Hrs.
Superior- North Sunflower Medical Center <sup>1</sup>	MP	Sunflower	M	517	664	Tu, Th., 8 Hrs.
Tallahatchie General Hospital	Н	Tallahatchie	M	212	213	M, 4 Hrs.
General Hospital S	Service Area	<u> </u>		21,758	22,586	
Baptist Memorial Hospital - Golden Triangle	Н	Lowndes	F(2)	2,845	2,942	M-Sun, 168 Hrs.
Baptist Memorial Hospital - North MS	Н	Lafayette	FM	2,698	2,759	Mon Sun., 168 Hrs.
Baptist Memorial Hospital - Calhoun	Н	Calhoun	M	192	255	M. & Thr., 10 Hrs.
Clay County Medical Corporation	Н	Clay	M	DNS	548	DNS
Gilmore Memorial Hospital, Inc.	Н	Monroe	M	996	974	M-F, 40 Hrs.
Imaging Center of Columbus	FS	Lowndes	F(2)	6,156	6,496	M-F, 50 Hrs.
Imaging Ctr. of Excellence Institute - MSU	FS	Oktibbeha	F	1,396	1,600	M-F, 45 Hrs.
Monroe Regional Hospital *	Н	Monroe	M	303	268	M,T, F 12 Hrs.
North Miss. Medical Center - Eupora ***	Н	Webster	M	637	574	M, Tu, & W 24 Hrs.
North Miss. Medical Center - West Point	Н	Clay	M	560	548	M-F, 40 Hrs.
Oktibbeha County Hospital	Н	Oktibbeha	F	2,616	2,620	M-F, 40 Hrs.
Trace Regional Hospital	Н	Chickasaw	M	309	316	Tu., Th. 16 Hrs.
SMI- Tyler Holmes Memorial Hospital	Н	Montgomery	M	237	235	W, 4 Hrs.
University of MS Medical Center - Grenada**	Н	Grenada	F	2,586	2,406	M-F, 40 Hrs.
SMI- Yalobusha Hospital	Н	Yalobusha	M	227	45	W, 4 Hrs.

F- Fixed unit

M-Mobile Unit

Type of Providers: H-Hospital, FS-Freestanding, and MP-Mobile Provider

Note: <sup>1</sup>Indicates Superior is the approved service provider.

<sup>&</sup>lt;sup>2</sup> Indicates Scott Medical Imaging is the approved service provider.

<sup>\*</sup>Pioneer Community Hospital changed its name to Monroe Regional Hospital.

<sup>\*\*</sup>Grenada Lake Medical Center changed its name to University of MS Medical Center-Grenada.

<sup>\*\*\*</sup>Webster Health Services changed its name to North MS Medical Center-Eupora.

<sup>\*\*\*\*</sup> Imaging Center of Gloster Creek Village did not start data collection until February 2017.

# Table 5-6 (continued) Location and Number of MRI Procedures by General Hospital Service Area FY 2015 and FY 2016

F Y 2015 and F Y 2016  Number of MRI						D 77 40 4
Facility	Type of Providers	County	Type of Equipment	Proced		Days/Hours of Operation
	Troviders		Equipment	2015	2016	2016
General Hospital Service A		1	ı	81,775	91,524	
Baptist Medical Center - Attala, Inc. *	Н	Attala	F	-	-	M, F 30 Hrs.
Baptist Medical Center - Leake, Inc.	Н	Leake	M	325	435	Tu., 4 Hrs.
Baptist Medical Center- Yazoo, Inc.	Н	Yazoo	M	572	614	Tu., Th., 8 Hrs.
Central MS Diagnostics, LLC	FS	Rankin	F	1,044	1,042	M-F, 40 Hrs.
Copiah County Medical Center	Н	Copiah	M	499	391	M,W,F 12 Hrs.
King's Daughters Medical Center	Н	Yazoo	F	2,650	2,831	Tues. & Th., 8 Hrs
Kosciusko Medical Clinic	FS	Attala	F	2,447	2,359	M-F, 45 Hrs.
Madison Radiological Group, LLC	FS	Madison	F	2,038	2,328	M-F, 40 Hrs.
Magee General Hospital	Н	Simpson	F	706	656	M-F, 40 Hrs.
Merit Health Central	Н	Hinds	F(2)	3,609	2,182	M-Sun, 90+ Hrs.
SMI- Merit Health Madison <sup>2</sup>	Н	Madison	F	220	304	M, W 8 Hrs.
Merit Health Rankin	Н	Rankin	F	610	762	M-F 40 Hrs.
Merit Health River Oaks	Н	Rankin	F	2,912	3,610	M-F, 50 Hrs.
Merit Health River Region	Н	Warren	F	2,466	2,526	M-F, 40 Hrs.
Miss. Baptist Medical Center	Н	Hinds	F(2)	7,402	8,289	M-Sat., M-F, 104 Hrs.
Miss. Diagnostic Imaging Center	FS	Rankin	F	2,233	2,237	M-F, 40 Hrs.
Mission Primary Care Clinic	FS	Warren	M	665	521	M-Th. 40 Hrs.
Miss. Sports Medicine & Orthopedic	FS	Hinds	F(2)	6,218	6,218	M-F, 90 Hrs.
Open MRI of Jackson	FS	Rankin	F	DNS	DNS	DNS
SE Lackey Memorial Hospital	Н	Scott	M	526	526	M, W, & Th, 24 Hrs.
Sharkey/Issaquena Community Hospital	Н	Sharkey	M	170	159	W., 4 hrs.
Southern Diagnostic Imaging	FS	Rankin	F	4,863	5,781	M-F, 80 Hrs.
SMI-Hardy Wilson Memorial Hospital <sup>2</sup>	Н	Copiah	M	469	361	M, Th.,& Fri. 12 Hrs.
SMI- Holmes County Hospital & Clinics	Н	Holmes	M	0	345	Thurs., 4 Hrs.
SMI- Leake Memorial Hospital	Н	Leake	M	327	429	Tu. 4 Hrs.
SMI- Madison River Oaks Medical Center	Н	Madison	M	208	289	Tu. Th., 8 Hrs
SMI-Ridgeland Diagnostic Center <sup>2</sup>	FS	Madison	M	739	627	M, W, & Th. 12 Hrs.
SMI- Scott County Hospital <sup>2</sup>	MP	Scott	M	18	145	F, 4 Hrs.
SMI-Simpson General Hospital <sup>2</sup>	MP	Simpson	M	28	114	Th., 4 Hrs.
St. Dominic's Jackson- Memorial Hospital	Н	Hinds	F(3)/M(1)	16,421	22,807	M-Sun., 328 Hrs.
St. Dominic's Madison Medical Imaging	FS	Madison	F	2,143	2,430	M-F, 40 Hrs.
University of MS Medical Center	Н	Hinds	F(6)	19,247	20,206	M-F 504 Hrs.
General Hospital Servi	ce Area 6	I	ı	13,614	14,183	
Anderson Regional Medical Center **	Н	Lauderdale	F(3)	4,705	4,393	M-F, 40 Hrs.
Anderson Regional Medical Center-South Campus	FS	Lauderdale	F(2)	33	26	
H. C. Watkins Memorial Hospital	Н	Clarke	M	0	141	Thr., 8 Hrs.
Imaging Center of Meridian, LLC	FS	Lauderdale	M	2,698	2,825	M-F, 45 Hrs.
John C Stennis Memorial Hospital	Н	Kemper	M	79	63	M-F, 45 Hrs.
Laird Hospital	Н	Newton	M	449	431	M,W, & F, 20 Hrs.
Neshoba County General Hospital	Н	Neshoba	F(4) M	1,342	1,507	M-F., 40Hrs.
Rush Foundation Hospital	FS	Lauderdale	F(2)	3,812	4,452	M-F, 130 Hrs.
SMI Newton Regional Hospital <sup>2</sup>	MP	Newton	M	176	29	M, 4 Hrs.
SMI-Wayne General Hospital <sup>2</sup>	MP	Wayne	M	320	316	M, 4 hrs.
5141 Wayne Ceneral Hospital	1711	" ayııc	171	320	310	171, 7 1115.

F- Fixed unit

M-Mobile Unit

Type of Providers: H-Hospital, FS-Freestanding, and MP-Mobile Provider

Note: <sup>1</sup>Indicates Superior is the approved service provider.

<sup>&</sup>lt;sup>2</sup> Indicates Scott Medical Imaging is the approved service provider.

<sup>\*</sup>Baptist Medical Center- Attala shares an MRI with Kosciusko Medical Clinic

<sup>\*\*</sup>Anderson Regional Medical Center South Campus uses Anderson Regional Medical Center's MRI

Table 5-6 (continued)
Location and Number of MRI Procedures by General Hospital Service Area
FY 2015 and FY 2016

Facility	Type of	County	Type of	Number Proce		Days/Hours of Operation
·	Providers		Equipment	2015	2016	2016
General Hospital S	ervice Area 7	•	,	7,265	8,521	
King's Daughters Medical Center	Н	Lincoln	F	2,650	2,831	M-F, 48 Hrs.
Merit Health Natchez	MP	Adams	F(2)	1,930	2,509	M-F, 50 Hrs.
SMI-Lawrence County Hospital <sup>2</sup>	MP	Lawrence	M	5	114	W, 4 Hrs.
SMI - Walthall County Hospital <sup>2</sup>	MP	Walthall	M	158	162	W, 4 Hrs.
Southwest MS Regional Medical Center	Н	Pike	F	2,522	2,905	M-F, 40 Hrs.
General Hospital S	ervice Area 8			31,516	32,759	
Forrest General Hospital	Н	Forrest	F(2)	5,514	6,061	M-Sun., 168 Hrs.
Hattiesburg Clinic, P.A.	FS	Forrest	F(4)	11,123	11,888	M-F 40 Hrs. & Sat. 38 Hrs.
Jefferson Davis Comm. Hospital	MP	Jeff Davis	M	121	105	Th., 4 Hrs.
Merit Health Wesley	Н	Lamar	F	2,426	2,325	M-F, 50 Hrs.
Open Air MRI of Laurel	FS	Jones	F	3,818	3,507	M-F, 40+ Hrs.
SMI- Marion General Hospital <sup>2</sup>	MP	Marion	M	275	280	Tu., 4 Hrs.
South Central Regional Medical Center	Н	Jones	F	2,229	2,229	M-F, 50 Hrs.
Southern Bone & Joint Specialist, PA	FS	Forrest	F(2)	6,010	6,364	M-Sat., 140 Hrs.
General Hospital S	ervice Area 9			29,142	31,290	
Cedar Lake MRI-Open MRI LLC	FS	Harrison	F	4,565	5,170	M-Sat, 78 Hrs.
Compass Imaging, LLC	FS	Harrison	M	534	633	M. & F, 16 Hrs.
Garden Park Medical Center	Н	Harrison	F	1,225	1,815	M-F, 40 Hrs.
George County Hospital	Н	George	F	773	749	M-F, 40 Hrs.
Hancock Medical Center	Н	Hancock	F	913	1,075	M-F, 40 Hrs.
Highland Community Hospital*	Н	Pearl River	M	1,513	1,657	M-Fri, 45 Hrs.
Memorial Hospital at Gulfport	Н	Harrison	F(2)	7,994	8,908	M-Sun, 154 Hrs.
Merit Health Biloxi	Н	Harrison	FM	1,937	1,876	M-F, 40 Hrs.
Ocean Springs Hospital	Н	Jackson	F(2)	4,296	4,135	M-F, 115+ Hrs.
OMRI, Inc. dba Open MRI	MP	Jackson	M(3)	N/A	N/A	M, Thr. 120 & F 160 Hrs.
Singing River Hospital	Н	Jackson	F(2) M	5,136	5,016	M-F, 155+ Hrs.
SMI- Stone County Hospital	Н	Stone	M	256	256	Tues., 4 Hrs.
State Total				238,772	256,199	

F- Fixed unit

M-Mobile Unit

Type of Providers: H-Hospital, FS-Freestanding, and MP- Mobile Provider

Note: <sup>2</sup> Indicates Scott Medical Imaging is the approved service provider.

Sources: Applications for Renewal of Hospital License for Calendar Years 2015; Fiscal Year 2016; FY 2017 MRI Utilization Survey

# 511 Invasive Digital Angiography (DA)

Invasive Digital Angiography (DA) is a diagnostic and catheter based therapeutic intravascular intervention imaging procedure that combines a digital processing unit with equipment similar to that used for standard fluoroscopic procedures.

Most invasive DA studies are appropriate as an outpatient procedure in a freestanding facility, where proper protocols have been met.

# 512 Positron Emission Tomography (PET)

Positron emission tomography (PET) is a minimally invasive imaging procedure in which positronemitting radionuclides, produced either by a cyclotron or by a radio-pharmaceutical producing generator, and a gamma camera are used to create pictures of organ function rather than structure. PET scans provide physicians a crucial assessment of the ability of specific tissues to function normally.

PET can provide unique clinical information in an economically viable manner, resulting in a diagnostic accuracy that affects patient management. PET scans provide diagnostic and prognostic patient information regarding cognitive disorders; for example, identifying the differences between Alzheimer's, Parkinson's, dementia, depression, cerebral disorders, and mild memory loss. PET scans also provide information regarding psychiatric disease, brain tumors, epilepsy, cardiovascular disease, movement disorders, and ataxia. Research shows that clinical PET may obviate the need for other imaging procedures.

PET installations generally take one of two forms: a scanner using only generator-produced tracers (basic PET unit) or a scanner with a cyclotron (enhanced PET unit). The rubidium-82 is the only generator approved by the FDA to produce radiopharmaceuticals. Rubidium limits PET services to cardiac perfusion imaging.

A PET scanner supported by a cyclotron can provide the capabilities for imaging a broader range of PET services, such as oncology, neurology, and cardiology. Manufacturers of PET equipment are providing more user-friendly cyclotrons, radiopharmaceutical delivery systems, and scanners which have drastically reduced personnel and maintenance requirements. These changes have made the cost of PET studies comparable to those of other high-technology studies.

Cardiology Associates of North Mississippi located in Tupelo, Mississippi (Lee County) has a fixed PET unit and performs Cardiac/PET procedures (pet scans/imaging of the heart). For FY 2013, Cardiology Associates of North Mississippi performed 1,596 procedures.

Table 5-7 presents the location, type (fixed or mobile), and utilization of PET equipment throughout the state in 2016.

Table 5-7 Location and Number of PET Procedures by Service Area FY 2016

F Y 20	710	1	1
Facility	County	Type of Equipment	Number of PET Procedures
General Hospital Serv	416		
Baptist Memorial Hospital - DeSoto	DeSoto	M	416
General Hospital Serv	vice Area 2	-	1,241
Magnolia Regional Health Center	Alcorn	M	344
North Mississippi Medical Center	Lee	F	897
General Hospital Serv	vice Area 3		605
Alliance Cancer Center- Clarks dale	Coahoma	M	DNS
Delta Regional Medical Center (Main Campus)	Washington	M	428
Greenwood Leflore Hospital	Leflore	M	177
General Hospital Serv	vice Area 4		1,374
Baptist Memorial Hospital - Golden Triangle	Lowndes	F	654
Baptist Memorial Hospital - North Miss	Lafayette	F	576
University of MS Medical Center- Grenada	Grenada	M	144
General Hospital Serv	vice Area 5		5,552
Merit Health Central	Hinds	F	166
Mississippi Baptist Medical Center	Hinds	F (2)	1,264
St. Dominic Jackson- Memorial Hospital	Hinds	F	1,731
University of MS Medical Center	HInds	F	2,391
Baptist Medical Center Attala *	Atttala	M	-
General Hospital Serv	vice Area 6		306
Anderson Regional Medical Center	Lauderdale	М	306
General Hospital Serv	645		
Merit Health Natchez	Adams	M	271
Southwest MS Regional Medical Center	Pike	M	374
General Hospital Serv	3,965		
Forrest General Hospital	Forrest	M	8
Hattiesburg Clinic, P.A. <sup>1</sup>	Forrest	F (2)	3,257
South Central Regional Medical Center	Jones	M	606
Merit Health Wesley	Lamar	M	94
General Hospital Serv	1,927		
Merit Health Biloxi	Harrison	M	130
Garden Park Medical Center	Harrison	M	75
Memorial Hospital at Gulfport	Harrison	F	1,001
Ocean Springs Hospital	Jackson	M	345
Singing River Hospital	Jackson	M	376
State Total			16,031

Note: <sup>1</sup> Indicates freestanding clinics.

Sources: Applications for Renewal of Hospital License for Calendar Years 2015; Fiscal Year 2016 Annual Hospital Report; FY 2017 PET Utilization Survey

<sup>\*</sup>Baptist Medical Center- Attala is CON approved for a mobile PET but did not utilize the service in 2016.

# 512.01 Certificate of Need Criteria and Standards for Magnetic Resonance Imaging Services (MRI)

**Note:** Should MSDH receive a CON application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until MSDH has developed and adopted CON criteria and standards. If MSDH has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of MSDH.

# 512.01.01 Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Magnetic Resonance Imaging (MRI) Equipment and/or the Offering of MRI Services

- 1. CON Review Requirements: The CON process regarding the acquisition or otherwise control of MRI equipment and/or the offering of MRI services involves separate requirements for CON review: (a) an entity proposing to acquire or otherwise control MRI equipment must obtain a CON to do so if the capital expenditure for the MRI unit and related equipment exceeds \$1,500,000; and (b) an entity proposing to offer MRI services which has not provided the service on a regular basis within the last twelve (12) months must obtain a CON before providing such services, regardless of the capital expenditure.
- CON Approval Preference: MSDH shall give preference to those applicants proposing to
  enter into joint ventures utilizing mobile and/or shared equipment. However, the applicant
  must meet the applicable CON criteria and standards provided herein and the general
  criteria and standards contained in the currently approved Mississippi Certificate of Need
  Review Manual.
- 3. <u>Mobile MRI</u>: For purposes of this Plan, a mobile MRI unit is defined as an MRI unit operating at two or more host sites and that has a central service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of MRI services at each host site on a regularly scheduled basis.
- 4. <u>Conversion to Fixed:</u> The conversion from mobile MRI service to fixed MRI service is considered the establishment of a new MRI service and requires CON review.
- 5. <u>Utilization of Existing Units</u>: No new MRI services shall be approved unless all existing MRI service in the applicant's defined service area performed an average of 1,700 MRI procedures per existing and approved MRI scanner during the most recent twelve (12) month reporting period and the proposed new services would not reduce the utilization of existing providers in the service area.

- 6. <u>Population-Based Formula:</u> MSDH shall use a population-based formula as presented at the end of this chapter when calculating MRI need. Also, the formula will use historical and projected use rates by service area and patient origin data. The population-based formula is based on the most recent population projections prepared by the State Data Center (University of Mississippi Center for Population Studies). The applicant shall project a reasonable population base to justify the provision of 2,700 procedures (or 1,700 procedures for rural hospitals) by the second year of operation.
- 7. <u>Mobile Service Volume Proration:</u> The required minimum service volumes for the establishment of services and the addition of capacity for mobile services shall be prorated on a "site by site" basis based on the amount of time the mobile services will be operational at each site.
- 8. Addition of a Health Care Facility: An equipment vendor who proposes to add a health care facility to an existing or proposed route must notify MSDH through the filing of a Determination of Non Reviewability of any proposed changes, i.e., additional health care facilities or route deviations, from those presented in the Certificate of Need application prior to such change.

# 512.01.02 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Magnetic Resonance Imaging (MRI) Equipment and/or the Offering of MRI Services

MSDH will review applications for a CON for the acquisition or otherwise control of MRI equipment and/or the offering of MRI services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans MSDH; and the specific criteria and standards listed below.

The acquisition or otherwise control of MRI equipment is reviewable if the equipment cost is in excess of \$1,500,000; if the equipment and/or service is relocated; and if the proposed provider of MRI services has not provided such services on a regular basis within the period of twelve (12) months prior to the time such services would be offered, regardless of the capital expenditure.

# 512.01.03 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of MRI Equipment

#### **Need Criterion 1: Minimum Procedures/Population**

The entity desiring to acquire or otherwise control the MRI equipment shall demonstrate a minimum of 2,700 procedures per year by the end of the second year of operation; provided, however, that MRI equipment exclusively servicing rural hospitals (those located outside U.S. Census Bureau Metropolitan Statistical Areas with 75 or less beds) shall be required to demonstrate a minimum of 1,700 procedures per year by the end of the second year of operation. This criterion includes both fixed and mobile MRI equipment. The applicant must show the methodology used for the projections.

- a. Applicants for non-hospital based MRI facilities may submit affidavits from referring physicians. MRI procedures projected in affidavits shall be based on actual MRI procedures referred during the year.
- b. The applicant shall document a reasonable population base to document that a minimum of 2,700 procedures will be performed per proposed MRI unit (or 1,700 procedures per year for a mobile MRI route exclusively serving rural hospitals).
- c. The applicant shall demonstrate that all existing units within its defined service area have performed an average of 1,700 procedures for the most recent 12-month period.

It is recognized that an applicant desiring to acquire or otherwise control an MRI unit may make or propose to make the MRI unit available to more than one provider of MRI services, some of which may be located outside of Mississippi. In such cases all existing or proposed users of the MRI unit must jointly meet the required service volume of 2,700 (or 1,700 for mobile MRI route exclusively serving rural hospitals) procedures annually. If the MRI unit in question is presently utilized by other providers of MRI services, the actual number of procedures performed by them during the most recent twelve (12) month period and/or documented projections of physician referrals may be used.

### **Need Criterion 2: Equipment Requirements**

In order to receive CON approval to acquire or otherwise control MRI equipment, the applicant shall provide a copy of the proposed contract and document the following:

- a. that the equipment is FDA approved;
- b. that only qualified personnel will be allowed to operate the equipment; and
- c. that if the equipment is to be rented, leased, or otherwise used by other qualified providers on a contractual basis, no fixed/minimum volume contracts will be permitted.

#### **Need Criterion 3: Data Requirements**

Applicants shall provide written assurance that they will record and maintain, at a minimum, the following information and make it available to MSDH:

- a. All facilities which have access to the equipment;
- b. Utilization by each facility served by the equipment, e.g., days of operation, number of procedures, and number of repeat procedures;
- c. Financial data, e.g., copy of contracts, fee schedule, and cost per scan; and
- d. Demographic and patient origin data for each facility.

In addition, if required by the Department, the above referenced information and other data pertaining to the use of MRI equipment will be made available to the MSDH within fifteen (15) business days of request. The required information may also be requested for entities outside of Mississippi that use the MRI equipment in question.

#### **Need Criterion 4: Business Registration**

The entity desiring to acquire or otherwise control the MRI equipment must be a registered entity authorized to do business in Mississippi.

### Need Criterion 5: CON Approval/Exemption for MRI Equipment

Before the specified equipment can be utilized, the applicant desiring to provide the MRI equipment shall have CON approval or written evidence that the equipment is exempt from CON approval, as determined by MSDH through a determination of reviewability. Each specified piece of equipment must be exempt from or have CON approval.

# 512.01.04 Certificate of Need Criteria and Standards for the Offering of Fixed or Mobile MRI Services

An entity proposing to offer MRI services shall obtain Certificate of Need (CON) approval before offering such services.

# **Need Criterion 1: Minimum Procedures/Population**

The entity desiring to offer MRI services must document that the equipment shall perform a minimum of 2,700 procedures (or 1,700 procedures for rural hospitals) by the end of the second year of operation. This criterion includes both fixed and mobile MRI equipment. The applicant must show methodology used for the projections.

- a. Applicants for non-hospital based MRI facilities may submit affidavits from referring physicians. MRI procedures projected in affidavits shall be based on actual MRI procedures referred during the year.
- b. The applicant shall document a reasonable population within its service area to justify 2,700 procedures per year per proposed MRI unit (1,700 procedures per year per proposed mobile MRI unit on a route exclusively serving rural hospitals).
- c. The applicant shall demonstrate that all existing units within its defined service area have performed an average of 1,700 procedures for the most recent 12-month period.

It is recognized that a particular MRI unit may be utilized by more than one provider of MRI services, some of which may be located outside of Mississippi. In such cases all existing or proposed providers of MRI services must jointly meet the required service volume of 2,700 (or 1,700 for mobile MRI route exclusively serving rural hospitals) procedures annually by the end of the second year of operation. If the MRI unit in question is presently utilized by other providers of MRI services, the actual number of procedures performed by them during the most recent 12-month period and/or documented projection of physician referrals may be used instead of the formula projections.

#### **Need Criterion 2: Availability of Diagnostic Imaging Modalities**

An applicant desiring to offer MRI services must document that a full range of diagnostic imaging modalities for verification and complementary studies will be available at the time MRI services begin. These modalities shall include, but not be limited to, computed tomography (full body), ultrasound, angiography, nuclear medicine, and conventional radiology.

#### **Need Criterion 3: Non-Discrimination**

All applicants proposing to offer MRI services shall give written assurance that, within the scope of its available services, neither the facility where the service is provided nor its participating medical personnel shall have policies nor procedures which would exclude patients because of race, color, age, sex, ethnicity, or ability to pay.

#### **Need Criterion 4: Staffing Requirements**

The applicant must document that the following staff will be available:

- a. Director A full-time, board eligible radiologist or nuclear medicine imaging physician, or other board eligible licensed physician whose primary responsibility during the prior three years has been in the acquisition and interpretation of clinical images. The Director shall have knowledge of MRI through training, experience, or documented post-graduate education. The Director shall document a minimum of one week of full-time training with a functional MRI facility.
- b. One full-time MRI technologist radiographer or a person who has had equivalent education, training, and experience, who shall be on-site at all times during operating hours. This individual must be experienced in computed tomography or other cross sectional imaging methods, or must have equivalent training in MRI spectroscopy.

#### **Need Criterion 5: Experimental Procedures**

The applicant shall document that when an MRI unit is to be used for experimental procedures with formal/approved protocols, a full-time medical physicist or MRI scientist (see definition in Glossary) with at least one year of experience in diagnostic imaging shall be available in the facility.

#### **Need Criterion 6: Data Requirements**

The applicant shall provide assurances that the following data regarding its use of the MRI equipment will be kept and made available to MSDH upon request:

- a. Total number of procedures performed
- b. Number of inpatient procedures
- c. Number of outpatient procedures

- d. Average MRI scanning time per procedure
- e. Average cost per procedure
- f. Average charge per procedure
- g. Demographic/patient origin data
- h. Days of operation

In addition to the above data recording requirements, the facility should maintain the source of payment for procedures and the total amounts charged during the fiscal year when it is within the scope of the recording system.

# Need Criterion 7: CON Approval/Exemption for MRI Equipment

Before the service can be provided, the CON applicant desiring to offer MRI services shall provide written evidence that the specified MRI equipment provider has received CON approval or is exempt from CON approval as determined by through a determination of non-reviewability. Each specified piece of equipment must be exempt from or have CON approval.

## 512.01.05 Population-Based Formula for Projection of MRI Service Volume

 $X * Y \div 1,000 = V$ 

Where, X = Applicant's Defined Service area population

Y = Mississippi MRI Use Rate\*

V = Expected Volume

\* Use Rate shall be based on information in the State Health Plan

# 513 Certificate of Need Criteria and Standards for Diagnostic and Therapeutic Imaging Services

**Note**: Should MSDH receive a CON application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until MSDH has developed and adopted CON criteria and standards. If MSDH has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of MSDH.

# 513.01 Digital Angiography Equipment and Services

# 513.01.01Policy Statement Regarding Certificate of Need Applications for the Acquisition or Control of Digital Angiography Equipment and/or the Offering of Invasive Digital Angiography Services

1. <u>Digital Angiography Equipment and Services in Ambulatory Surgery Centers:</u> Applicants proposing the acquisition or otherwise control of Digital Angiography equipment and/or the offering of invasive digital angiography services in a single specialty ambulatory surgery center must apply for a certificate of need before providing such services.

# 513.01.02Certificate of Need Criteria and Standards for Invasive Digital Angiography in a Hospital

MSDH will review applications for a CON for the acquisition or otherwise control of Digital Angiography (DA) equipment and associated costs under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for Certificate of Need according to the general criteria listed in the Mississippi Certificate of Need Review Manual; all adopted rules, procedures, and plans of MSDH; and the specific criteria and standards listed below.

CON review is required when the capital expenditure for the purchase of Digital Angiography equipment and associated costs exceed \$1,500,000, or when the equipment is to be used for invasive procedures, i.e., the use of catheters. The offering of diagnostic and therapeutic intravascular intervention imaging services of an invasive nature, i.e. invasive digital angiography, is reviewable if those services have not been provided on a regular basis by the proposed provider of such services within the period of twelve (12) months prior to the time such services would be offered regardless of the capital expenditure.

#### **Need Criterion 1: Staffing Requirements**

The applicant for invasive DA services shall demonstrate that proper protocols for screening and medical specialty backup are in place before services are rendered by personnel other than those with specialized training.

For example, if a radiologist without specialized training in handling cardiac arrhythmia is to perform a procedure involving the heart, a cardiologist/cardiosurgeon must be available for backup.

The protocols shall include, but are not limited to, having prior arrangements for backup from:

- a. a cardiologist/cardiosurgeon for procedures involving the heart;
- b. a neurologist/neurosurgeon for procedures involving the brain; and

c. a vascular surgeon, cardiologist, radiologist or nephrologist credentialed and accredited for interventional peripheral vascular procedures.

## **Need Criterion 2: CON Exemption**

Before utilizing or providing the equipment or service, the applicant desiring to provide the digital angiography equipment or invasive DA services shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by MSDH through a determination of reviewability.

# 513.01.03 Certificate of Need Criteria and Standards for Invasive Digital Angiography (DA) in a Freestanding Facility

#### **Need Criterion 1: Staffing Requirements**

- a. The applicant for invasive DA services shall demonstrate that proper protocols for screening and medical specialty backup are in place before services are rendered by personnel other than those with specialized training. The protocols shall include, but are not limited to, having prior arrangements for consultation/backup from a vascular surgeon, cardiologist, radiologist or nephrologist credentialed and accredited for interventional peripheral vascular procedures.
- b. Identify physicians in the group and state which physicians(s) will perform intravascular interventions using DA. Certify that:
  - i. Each physician will maintain medical staff privileges at a full service hospital; or
  - ii. At least one member of the physician group has staff privileges at a full service hospital and will be available at the facility or on call within a 30-minute travel time of the full service hospital during the hours of operation of the facility.

### **Need Criterion 2: Types of Procedures**

- a. Procedures in a freestanding facility are generally non-emergent nor life threatening in nature and require a patient stay of less than 24 consecutive hours. The procedures shall not be of a type that:
  - i. Generally result in blood loss of more than ten percent of estimated blood volume in a patient with a normal hemoglobin;
  - ii. Require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; or
  - iii. Involve major blood vessels.
    - Major blood vessels are defined as the group of critical arteries and veins including the aorta, coronary arteries, pulmonary arteries, superior and inferior vena cava, pulmonary veins, carotid arteries, and any intracerebral artery or vein.

b. Percutaneous endovascular interventions of the peripheral vessels not excluded in a.iii.1. above are permitted to be performed in a freestanding facility. These procedures are defined as procedures performed without open direct visualization of the target vessel, requiring only needle puncture of an artery or vein followed by insertion of catheters, wires, or similar devices which are then advanced through the blood vessels using imaging guidance. Once the catheter reaches the intended location, various maneuvers to address the diseased area may be performed which include, but are not limited to, injection of contrast for imaging, ultrasound of the vessel, treatment of vessels with angioplasty, artherectomy, covered or uncovered stenting, intentional occlusion of vessels or organs (embolization), and delivering of medications, radiation, or other energy such as laser, radiofrequency, or cryo.

#### **Need Criterion 3: Transfer Agreement**

The applicant must certify that the proposed facility will have a formal transfer agreement with a full service hospital to provide services which are required beyond the scope of the freestanding facility's programs.

# **Need Criterion 4: CON Exemption**

Before utilizing or providing the equipment or service, the applicant desiring to provide the digital angiography equipment or invasive DA services shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by MSDH through a determination of reviewability.

### 513.02 Positron Emission Tomography (PET) Equipment and Services

# 513.02.01 Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of a Positron Emission Tomography (PET) Scanner and Related Equipment including Cardiac only PET Scanner

- 1. <u>CON Review Requirements:</u> Applicants proposing the acquisition or otherwise control of a PET scanner shall obtain a CON to do so if the capital expenditure for the scanner and related equipment exceeds \$1,500,000.
- 2. <u>Indigent/Charity Care:</u> An applicant shall be required to provide a "reasonable amount" of indigent/charity care as described in Chapter 1 of this Plan.
- 3. <u>Service Areas</u>: The state as a whole shall serve as a single service area in determining the need for a PET scanner. In the case of Cardiac only PET Scanner, the service area will be the General Hospital Service Areas.
- 4. <u>Equipment to Population Ratio</u>: The need for a PET scanner is estimated to be one scanner per 300,000 population. MSDH will consider out-of-state population in determining need only when the applicant submits adequate documentation acceptable to MSDH, such as valid patient origin studies. In the case of Cardiac only PET Scanner, this policy will not apply.

- 5. Access to Supplies: Applicants must have direct access to appropriate radiopharmaceuticals.
- 6. <u>Services and Medical Specialties Required</u>: The proposed PET units must function as a component of a comprehensive inpatient or outpatient diagnostic service. The proposed PET unit must have the following modalities (and capabilities) on-site or through contractual arrangements:
  - a. Computed tomography (whole body)
  - b. Magnetic resonance imaging (brain and whole body)
  - c. Nuclear medicine (cardiac, SPECT)
  - d. Conventional radiography
  - e. The following medical specialties during operations hours:
    - i. Cardiology
    - ii. Neurology
    - iii. Neurosurgery
    - iv. Oncology
    - v. Psychiatry
    - vi. Radiology
- 7. <u>Hours of Operation</u>: PET facilities should have adequate scheduled hours to avoid an excessive backlog of cases.
- 8. <u>CON Approval Preference</u>: MSDH may approve applicants proposing to enter ventures utilizing mobile and/or shared equipment.
- 9. <u>CON Requirements</u>: The criteria and standards contained herein pertain to both fixed and/or mobile PET scanner equipment.
- 10. <u>CON Exemption</u>: Nothing contained in these CON criteria and standards shall preclude the University of Mississippi School of Medicine from acquiring and operating a PET scanner and a Cardiac only PET Scanner, provided the acquisition and use of such equipment is justified by the School's teaching and/or research mission and complies with the teaching exception as outlined in section 102.02 of this Plan. However, the requirements listed under the section regarding the granting of "appropriate scope of privileges for access to the scanner to any qualified physician" must be met. MSDH shall not consider utilization of equipment/services at any hospital owned and operated by the state or its agencies when reviewing CON applications.
- 11. <u>Addition to a Health Care Facility</u>: An equipment vendor who proposes to add a health care facility to an existing or proposed route must notify MSDH by submitting a determination

- of reviewability for any proposed changes from those presented in the CON application prior to such change, i.e., additional health care facilities or route deviations.
- 12. <u>Equipment Registration</u>: The applicant must provide the Department with the registration/serial number of the CON-approved PET scanner.
- 13. <u>Certification</u>: If a mobile PET scanner, the applicant must certify that only the single authorized piece of equipment and related equipment vendor described in the CON application will be utilized for the PET service by the authorized facility/facilities.
- 14. <u>Conversion from mobile to fixed service</u>: The conversion from mobile PET service site to a fixed PET service site is considered the establishment of a new service and requires CON review.

# 513.02.02 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of a Positron Emission Tomography (PET) Scanner and Related Equipment including Cardiac only PET Scanner

MSDH will review applications for a Certificate of Need for the acquisition or otherwise control of a PET scanner and related equipment under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for Certificate of Need according to the general review criteria listed in the Mississippi Certificate of Need Review Manual; all adopted rules, procedures, and plans of MSDH; and the specific criteria and standards listed below.

The acquisition or otherwise control of a PET scanner and related equipment is reviewable if the equipment cost is in excess of \$1,500,000, or if the equipment is relocated. The offering of PET services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered, regardless of the capital expenditure.

# **Need Criterion 1: Minimum Procedures/Population**

- a. The entity desiring to acquire or to otherwise control the PET scanner must project a minimum of 1,000 clinical procedures per year and must show the methodology used for the projection.
- b. The applicant shall document a minimum population of 300,000 per PET scanner unit. The Division of Health Planning and Resource Development population projections shall be used. In the case of Cardiac only PET Scanner, this Criterion will not apply.

# **Need Criterion 2: Business Registration**

The entity desiring to acquire or otherwise control the PET equipment must be a registered entity authorized to do business in Mississippi.

## **Need Criterion 3: Approval of Additional PET Equipment**

MSDH will approve additional PET equipment in a service area with existing equipment only when it is demonstrated that the existing PET equipment in that service area is performing an average of 1,500 clinical procedures per PET unit per year (six clinical procedures per day x 250 working days per year). For purposes of this Criterion, PET and Cardiac only PET are to be evaluated separately.

#### Need Criterion 4: Division of Radiological Health Approval

The application shall affirm that the applicant shall receive approval from the Division of Radiological Health for the proposed site, plans, and equipment before service begins.

# **Need Criterion 5: Data Requirements**

The applicant shall provide assurances that the following data regarding the PET equipment will be kept and made available to MSDH upon request:

- a. Total number of procedures performed;
- b. Total number of inpatient procedures (indicate type of procedure);
- c. Total number of outpatient procedures (indicate type of procedure);
- d. Average charge per specific procedure;
- e. Hours of operation of the PET unit;
- f. Days of operation per year; and
- g. Total revenue and expense for the PET unit for the year.

#### **Need Criterion 6: Fixed/Minimum Value Contracts**

The applicant shall provide a copy of the proposed contract and document that if the equipment is to be rented, leased, or otherwise used by other qualified providers on a contractual basis, no fixed/minimum volume contracts will be permitted.

### Need Criterion 7: CON Approval/Exemption for PET Equipment

Before the specified equipment can be utilized, the applicant desiring to provide the PET equipment shall have CON approval or written evidence that the equipment is exempt from CON approval as determined by MSDH. Each specified piece of equipment must be exempt from or have CON approval.

# 513.02.03 Certificate of Need Criteria and Standards for Offering of Fixed or Mobile Positron Emission Tomography (PET) Services including Cardiac only PET Scanner

The offering of fixed or mobile PET services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

#### **Need Criterion 1: Minimum Procedures**

The entity desiring to offer PET services must document that the equipment shall perform a minimum of 1,000 clinical procedures per year and must show the methodology used for the projection.

# **Need Criterion 2: PET Equipment Utilized by Multiple Providers**

It is recognized that a particular PET unit may be utilized by more than one provider of PET services, some of which may be located outside of Mississippi. In such cases all existing or proposed providers of PET services utilizing the same PET unit must jointly meet the required service volume of 1,000 procedures annually. If the PET unit in question is presently utilized by other providers of PET services, the actual number of procedures performed by them during the most recent 12-month period may be used.

### **Need Criterion 3: Quality Control and Environmental Requirements**

An applicant proposing to provide new or expanded PET services must include written assurances in the application that the service will be offered in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing agencies' requirements. The following areas are to be addressed:

- a. Quality control and assurance of radiopharmaceutical production of generator or cyclotron-produced agents;
- b. Quality control and assurance of PET tomograph and associated instrumentation;
- c. Radiation protection and shielding; and
- d. Radioactive emissions to the environment.

# Need Criterion 4: Division of Radiological Health Approval

The application shall affirm that the applicant shall receive approval from the Division of Radiological Health for the proposed site, plans, and equipment before service begins.

### **Need Criterion 5: Provision of On-Site Medical Cyclotron**

The applicant shall document provision of an on-site medical cyclotron for radionuclide production and a chemistry unit for labeling radiopharmaceuticals; or an on-site rubidium-82 generator; or access to a supply of cyclotron-produced radiopharmaceuticals from an off-site

medical cyclotron and a radiopharmaceutical production facility within a two-hour air transport radius.

# **Need Criterion 6: Staffing Requirements**

Applicants for PET shall document that the necessary qualified staff are available to operate the proposed unit. The applicant shall document the PET training and experience of the staff. The following minimum staff shall be available to the PET unit:

- a. If operating a fixed PET unit, one or more nuclear medicine imaging physician(s) available to the PET unit on a full-time basis (e.g., radiologist, nuclear cardiologist) who have been licensed by the state for the handling of medical radionuclides and whose primary responsibility for at least a one-year period prior to submission of the CON application has been in acquisition and interpretation of tomographic images. This individual shall have knowledge of PET through training, experience, or documented postgraduate education. The individual shall also have training with a functional PET facility.
- b. If operating a cyclotron on site, a qualified PET radiochemist or radiopharmacist personnel, available to the facility during PET service hours, with at least one year of training and experience in the synthesis of short-lived positron emitting radiopharmaceuticals. The individual(s) shall have experience in the testing of chemical, radiochemical, and radionuclidic purity of PET radiopharmaceutical syntheses.
- c. Qualified engineering and physics personnel, available to the facility during PET service hours, with training and experience in the operation and maintenance of the PET equipment. Engineering personnel are not required on-site for mobile PET units.
- d. Qualified radiation safety personnel, available to the facility at all times, with training and experience in the handling of short-lived positron emitting nuclides. If a medical cyclotron is operated on-site, personnel with expertise in radiopharmacy, radiochemistry, and medical physics would also be required.
- e. Certified nuclear medicine technologists with expertise in computed tomographic nuclear medicine imaging procedures, at a staff level consistent with the proposed center's expected PET service volume.
- f. Other appropriate personnel shall be available during PET service hours which may include certified nuclear medicine technologists, computer programmers, nurses, and radio-chemistry technicians.

#### **Need Criterion 7: Management of Medical Emergencies**

The applicant shall demonstrate how medical emergencies within the PET unit will be managed in conformity with accepted medical practice.

### **Need Criterion 8: Accommodating Referred Patients**

The applicant shall affirm that, in addition to accepting patients from participating institutions, facilities performing clinical PET procedures shall accept appropriate referrals from other local providers. These patients shall be accommodated to the extent possible by extending the hours of service and by prioritizing patients according to standards of need and appropriateness rather than source of referral.

## **Need Criterion 9: Medical Necessity**

The applicant shall affirm that protocols will be established to assure that all clinical PET procedures performed are medically necessary and cannot be performed as well by other, less expensive, established modalities.

#### **Need Criterion 10: Notification of Procedures Offered**

Applicants will be required to maintain current listings of appropriate PET procedures for use by referring physicians.

## **Need Criterion 11: Data Requirements**

The applicant shall provide assurances that the following data regarding the PET service will be kept and made available to MSDH upon request:

- a. Total number of procedures performed; total number of inpatient procedures (indicate type of procedure);
- b. Total number of outpatient procedures (indicate type of procedure);
- c. Average charge per specific procedure;
- d. Hours of operation of the PET unit;
- e. Days of operation per year; and
- f. Total revenue and expense for the PET unit for the year.

### **Need Criterion 12: CON Approval/Exemption for PET Equipment**

Before the specified service can be provided, the applicant desiring to offer the PET service shall provide written evidence that the specified PET equipment provider has CON approval or written evidence that the equipment is exempt from CON approval as determined by MSDH through a determination of reviewability. Each specified piece of equipment must be exempt from or have CON approval.

### 514 Cardiac Catheterization

Cardiac catheterization is an integral part of cardiac evaluation and brings together two disciplines: cardiac catheterization (the evaluation of cardiac function) and angiography (X-ray demonstration of cardiac anatomy). Cardiac catheterization includes various therapeutic interventions, including but not limited to: percutaneous coronary interventions (PCI), thrombolysis of coronary clots in evolving myocardial infarctions, electrical ablation of abnormal conduction pathways, and closure of patent ductus arteriosus in infants.

Any facility performing diagnostic cardiac catheterizations without open-heart surgery capability must maintain formal referral agreements with a nearby facility to provide emergency cardiac services, including open-heart surgery. Such a facility must also delineate the steps it will take to ensure that high-risk patients are not catheterized in the facility. Additionally, a facility without open-heart surgery capability must document that more complex procedures, except for percutaneous coronary interventions (PCI) as provided herein, are not performed in the facility. Such procedures include, but are not limited to: transseptal puncture, transthoracic left ventricular puncture, myocardial biopsy, trans catheter aortic valve replacement (TAVR), and left atrial occlusion devices.

Section 41-7-191(1)(d), Mississippi Code of 1972, as amended, requires Certificate of Need review for the establishment and/or offering of cardiac catheterization services if the proposed provider has not offered such services on a regular basis within 12 months prior to the time the services would be offered. Table 5-8 presents the utilization of cardiac catheterization services in Fiscal Years 2015 and 2016.

**Table 5-8** Cardiac Catheterizations by Facility and Type by Cardiac Catheterization/Open Heart Planning Area (CC/OHSPA) FY 2015 and FY 2016

Facility	County	Total Adult Procedures		Total Pediatric Procedures		Total PTCA Procedures	
		2015	2016	2015	2016	2015	2016
CC/OHSPA 1		2,092	2,497	0	0	872	1,154
Baptist Memorial Hospital-DeSoto	DeSoto	2,060	2,226	0	0	870	767
Methodist Healthcare Olive Branch Hospital	DeSoto	32	271	0	0	2	387
CC/OHSPA 2		6,545	6,464	0	0	464	386
Magnolia Regional Health Center	Alcorn	3,285	2,949	0	0	99	73
North Mississippi Medical Center	Lee	3,260	3,515	0	0	365	313
North Mississippi State Hospital*	Lee	0	0	0	0	0	0
CC/OHSPA 3		1,242	1,138	0	0	143	152
Allegiance Specialty Hospital of Greenville	Washington	0	0	0	0	0	0
Delta Regional Medical Center	Washington	752	780	0	0	143	152
Greenwood Leflore Hospital*	LeFlore	95	75	0	0	0	0
Northwest Mississippi Medical Center*	Coahoma	395	283	0	0	0	0
CC/OHSPA 4		2,394	2,634	0	0	749	748
Baptist Memorial Hospital-Golden Triangle	Lowndes	1,118	1,225	0	0	311	359
Baptist Memorial Hospital-N. Mississippi	Lafayette	1,167	1,266	0	0	438	389
UMMC Grenada*	Grenada	109	143	0	0	0	0
CC/OHSPA 5		24,302	20,046	1,573	1,895	2,937	3,446
Merit Health Central	Hinds	668	668	0	0	149	149
Merit Health River Oaks*	Rankin	0	0	0	0	125	125
Mississippi Baptist Medical Center	Hinds	4,275	4,449	0	0	1,259	1,367
Merit Health River Region	Warren	2,023	808	0	0	273	0
Promise Hospital of Vicksburg	Warren	0	0	0	0	0	0
Select Specialty Hospital-Belhaven, LLC	Hinds	0	0	0	0	0	0
Select Specialty Hospital - Jackson	Hinds	0	0	0	0	0	0
St. Dominic-Jackson Memorial Hospital	Hinds	10,052	11,596	0	0	911	782
University of MS Medical Center	Hinds	7,284	2,525	1,573	1895	220	1,023
CC/OHSPA 6		932	845	0	0	10	8
Anders on Regional Medical Center	Lauderdale	0	0	0	0	0	0
Anders on Regional Medical Center -South*	Lauderdale	0	0	0	0	0	0
Rush Foundation Hospital	Lauderdale	932	845	0	0	10	8
CC/OHSPA 7		949	811	0	0	34	22
Merit Health Natchez*	Adams	0	0	0	0	0	0
SW Miss Regional Medical Center	Pike	949	811	0	0	34	22
CC/OHSPA 8		3,968	5,177	0	0	1,363	1,689
Forrest General Hospital	Forrest	2,716	3,413	0	0	1,058	1226
Regency Hospital of Hattiesburg*	Forrest	0	0	0	0	0	0
South Central Regional Medical Center*	Jones	0	564	0	0	0	0
Merit Health Wesley	Lamar	1,252	1,200	0	0	305	463
CC/OHSPA 9		5,092	4,878	0	0	2,621	2,382
Merit Health Biloxi*	Harrison	50	15	0	0	0	0
Memorial Hospital at Gulfport	Harrison	2,679	2,744	0	0	1,112	1,074
Ocean Springs Hospital	Jackson	1,382	1,250	0	0	940	816
Select Specialty Hospital-Gulf Coast	Harrison	0	0	0	0	0	0
Singing River Hospital	Jackson	981	869	0	0	569	492
State Total	•	47,581	44,490	1,573	1,895	9,193	9.987

\* Diagnostic Cauterizations Only Source: Applications for Renewal of Hospital License for Calendar Year 2015/2016; FY 2016/2017 Annual Hospital Report

# Certificate of Need Criteria and Standards for Cardiac Catheterization Services and Open-Heart Surgery Services

**Note:** Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

# Joint Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Cardiac Catheterization Equipment and/or the Offering of Cardiac Catheterization Services and/or the Acquisition of Open-Heart Surgery Equipment and/or the Offering of Open-Heart Surgery Services

Heart disease remains the leading cause of death in Mississippi. However, it should be noted that the State has seen a decrease in mortality rates in the last few years. From 2004 to 2013, the mortality rate for African American women decreased by 25% per 100,000 and the total mortality rate decreased by 19.6% per 100,000. Studies show that minorities have a higher cardiovascular death rate than whites and are less likely to receive cardiac catheterization and open-heart surgery services than are whites. The disproportionate impact on minorities' health status in general is recognized elsewhere in this State Health Plan.

Innovative approaches to address these problems in the cardiac area are needed. It has been shown that statistical methods, such as population base and optimum capacity at existing providers, are not accurate indicators of the needs of the underserved, nor do they address the accessibility of existing programs to the underserved. The goal of these revisions to the State Health Plan is to improve access to cardiac care and to encourage the establishment of additional cardiac catheterization and open-heart surgery programs within the state that can serve the poor, minorities, and the rural population in greater numbers.

MSDH also adopted a provision that it shall not consider utilization of equipment/services at any hospital owned and/or operated by the state or its agencies when reviewing CON applications. MSDH further adopted standards requiring an applicant to report information regarding catheterization and open-heart programs so as to monitor the provision of care to the medically underserved and the quality of that care.

MSDH shall interpret and implement all standards in this Plan in recognition of the stated findings and so as to achieve the stated goal.

# Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Cardiac Catheterization Equipment and/or the Offering of Cardiac Catheterization Services

- <u>Cardiac Catheterization Services</u>: For purposes of the following CON criteria and standards
  the term "cardiac catheterization services" or "catheterization services" shall include three
  levels of cardiac catheterization services an applicant may provide: diagnostic cardiac
  catheterization services, percutaneous coronary intervention (PCI) in a hospital without onsite cardiac surgery, or therapeutic cardiac catheterization services.
  - a. <u>Diagnostic cardiac catheterization services</u> are defined as, and refer to, cardiac catheterization services which are performed for the purpose of diagnosing, identifying, or evaluating cardiac related illness or disease. Diagnostic cardiac catheterization services include, but are not limited to, left heart catheterizations, right heart catheterizations, left ventricular angiography, coronary procedures, and other cardiac catheterization services of a diagnostic nature.
  - b. <u>Percutaneous coronary intervention (PCI) services</u> in a hospital without on-site cardiac surgery are defined as, and refer to, those therapeutic cardiac catheterization services involving primary and elective PCIs but not involving transseptal puncture, transthoracic left ventricular puncture, myocardial biopsy, and any other procedure that is currently defined as a structural heart disease procedure.
  - c. <u>Therapeutic cardiac catheterization services</u> are defined as, and refer to, cardiac catheterization services which are performed for the purpose of actively treating, as opposed to merely diagnosing, cardiac-related illness or disease. Therapeutic cardiac catheterization services include, but are not limited to,-all PCIs (including primary and elective), transseptal puncture, transthoracic left ventricular puncture, myocardial biopsy, and any procedure that is currently defined as a structural heart disease procedure.
- 2. Open-Heart Surgery Capability: MSDH shall not approve CON applications for the establishment of therapeutic cardiac catheterization services at any facility that does not have open-heart surgery capability; i.e., new therapeutic cardiac catheterization services may not be established and existing therapeutic cardiac catheterization services may not be extended without approved and operational open-heart surgery services in place. This policy does not preclude approval of a Certificate of Need application proposing the concurrent establishment of both therapeutic cardiac catheterization and open-heart surgery services. This policy also does not preclude approval of a Certificate of Need application to perform percutaneous coronary intervention (PCI) services in a hospital without on-site cardiac surgery.
- 3. <u>Service Areas</u>: The State has nine designated Cardiac Catheterization/Open-Heart Surgery Planning Areas (CC/OHSPAs) presented in the Open Heart Surgery section of this chapter of the Plan. Map 5-2 shows the CC/OHSPAs.
- 4. <u>Pediatric Cardiac Catheterization</u>: Because the number of pediatric patients requiring study is relatively small, the provision of cardiac catheterization for neonates, infants, and young children shall be restricted to those facilities currently providing the service. National standards indicate that a minimum of 150 cardiac catheterization cases should be done per

- year and that catheterization of infants should not be performed in facilities which do not have active pediatric cardiac-surgical programs.
- 5. Present Utilization of Cardiac Catheterization Equipment/Services: MSDH shall consider utilization of existing equipment/services and the presence of valid CONs for equipment/services within a given CC/OHSPA when reviewing CON applications. MSDH shall not consider utilization of equipment/services at any hospital owned and/or operated by the state or its agencies when reviewing CON applications. MSDH may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.
- 6. Minimum Caseload: Applicants for a diagnostic cardiac catheterization Certificate of Need must be able to project a caseload of at least 300 diagnostic catheterizations per year per year by the end of the third year of operation. Applicants for a therapeutic cardiac catheterization Certificate of Need must be able to project a caseload of at least 450 catheterizations, diagnostic and therapeutic, per year by the end of the third year of operation. Applicant for a Certificate of Need to provide PCI services in a hospital without on-site cardiac surgery must be able to project a caseload of at least 300 catheterizations, diagnostic and PCI, with at least 100 being PCIs, per year by the end of the third year of operation.
- 7. Residence of Medical Staff: Cardiac catheterizations must be under the control of and performed by personnel living and working within the specific hospital area. No site shall be approved for the provision of services by traveling teams.
- 8. <u>Hospital-Based</u>: All cardiac catheterizations and open-heart surgery services shall be located in acute care hospitals. MSDH shall not approve Certificate of Need applications proposing the establishment of cardiac catheterization/open-heart surgery services in freestanding facilities or in freestanding ambulatory surgery facilities.
- 9. Conversion of Existing Therapeutic Cardiac Catheterization Services to PCI Services in a Hospital without On-Site Cardiac Surgery Capabilities: A hospital currently providing therapeutic cardiac catheterization services may convert their cardiac catheterization program to provide PCI services in the hospital without on-site cardiac surgery capability without certificate of need review; provided, however, that the facility shall submit an application for determination of non-reviewability prior to eliminating on-site cardiac surgery. The hospital must attest in the application for determination of non-reviewability that it will meet the CON criteria and standards as set out in Rule 515.04 of this *Plan*. If, at any time, the hospital goes 12 consecutive months of providing PCI services without on-site cardiac surgery, the hospital wants to convert back to a therapeutic cardiac catheterization program, the hospital must submit a certificate of need application for review.

# 515.03 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Diagnostic Cardiac Catheterization Equipment and/or the Offering of Diagnostic Cardiac Catheterization Services

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of diagnostic cardiac catheterization equipment and/or the offering of diagnostic cardiac catheterization services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review

applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate* of Need Review Manual; all adopted rules, procedures and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of diagnostic cardiac catheterization equipment is reviewable if the equipment costs exceed \$1,500,000. The offering of diagnostic cardiac catheterization services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered, regardless of the capital expenditure.

#### **Need Criterion 1: Minimum Procedures**

An applicant proposing the establishment of diagnostic cardiac catheterization services only shall demonstrate that the proposed equipment/service utilization will be a minimum of 300 diagnostic cardiac catheterizations per year by its third year of operation.

#### **Need Criterion 2: Staffing Standards**

The applicant shall document that it has, or can obtain, the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs.

#### **Need Criterion 3: Recording and Maintenance of Data**

Applicants shall provide, as required under licensure standards, written assurance that they will record and maintain utilization data for diagnostic cardiac catheterization procedures (e.g., morbidity data, number of diagnostic cardiac catheterization procedures performed, and mortality data, all reported by race, sex, and payor status) and make such data available to the Mississippi State Department of Health annually.

### **Need Criterion 4: Referral Agreement**

An applicant proposing the establishment of diagnostic cardiac catheterization services only shall document that a formal referral agreement with a facility for the provision of emergency cardiac services (including open-heart surgery) will be in place and operational at the time of the inception of cardiac catheterization services.

#### **Need Criterion 5: Patient Selection**

An applicant proposing to provide diagnostic cardiac catheterization services must (a) delineate the steps which will be taken to insure that high risk patients are not catheterized in the facility, and (b) certify that therapeutic cardiac catheterization services and/or PCI services in a hospital without on-site cardiac surgery will not be performed in the facility unless and until the applicant has received CON approval to provide said services.

#### **Need Criterion 6: Regulatory Approval**

Before utilizing or providing the equipment or service, the applicant desiring to provide the diagnostic cardiac catheterization equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by the

Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

515.04 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Therapeutic Cardiac Catheterization Equipment for the Performance of PCI Services in a Hospital Without On-Site Cardiac Surgery and/or the Offering Of PCI Services in a Hospital Without In-Site Cardiac Surgery

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of therapeutic cardiac catheterization equipment for the performance or offering of PCI services in a hospital without on-site cardiac surgery under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of therapeutic cardiac catheterization equipment for the performance of PCI services in a hospital without on-site cardiac surgery is reviewable if the equipment costs exceed \$1,500,000. The offering of PCI services in a hospital without on-site cardiac surgery is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered, regardless of the capital expenditure.

#### **Need Criterion 1: Minimum Procedures**

An applicant proposing the establishment of PCI services in a hospital without on-site cardiac surgery shall demonstrate that the proposed equipment/service utilization will be a minimum of 300 cardiac catheterizations, both diagnostic and PCI, with at least 100 being total PCIs, per year by its third year of operation. Applicants must certify they will submit volume data to demonstrate and verify the utilization of the service at a minimum of every three (3) years.

# **Need Criterion 2: Staffing Requirements**

The applicant shall document that it has, or can obtain, the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs.

# **Need Criterion 3: Staff Residency**

The applicant shall certify that medical staff performing PCI procedures shall be onsite within thirty (30) minutes.

### **Need Criterion 4: Recording and Maintenance of Data**

In addition to the certification in Need Criterion 1, applicants shall provide, as required under licensure standards, written assurance that they will record and maintain separate utilization data for diagnostic and PCI catheterization procedures (e.g., morbidity data, number of diagnostic cardiac catheterization and PCI procedures performed and mortality data, all reported by race, sex and payor status) and make that data available to the Mississippi State Department of Health annually.

# **Need Criterion 5: Open-Heart Surgery**

An applicant proposing the establishment of PCI services without on-site cardiac surgery shall:

- a. Document that open-heart surgery services will be available through a formal emergency transfer agreement to a hospital providing open heart surgery. Such transfer must be done at a minimum of less than 120 minutes to accomplish transfer from the onset of PCI complications to cardiopulmonary bypass. Transporting of the patient to the receiving hospital must include the capability to provide an intra-aortic balloon pump (IABP).
- b. Programs must project and annually perform a minimum of 100 total PCIs per year to include at a minimum 12 primary PCIs per year by the end of the third year of operation. New programs should have three years to reach the absolute minimum volume, but after that, programs failing to reach this volume for two consecutive years should not remain open. MSDH has the discretion under a finding of rare or unique circumstances to grant an exception to the above based on a finding of need of access and quality of care by the program.
- c. Certify that the proposed primary operators for the service have a life-time experience of greater than 150 total PCIs with acceptable outcomes as primary operator after completing a cardiology fellowship. Successful completion of an Interventional Cardiology fellowship is considered adequate certification.
- d. New and Existing Programs must actively participate in the STEMI ("ST"-Segment Elevation Myocardial Infarction) Network, including, but not limited to, the submission of data to the STEMI databank.
- e. At the present time, there is no justification for a PCI program without on-site surgery to perform only elective procedures or not provide availability to primary PCI 24 hours/365 days per year. The Mississippi State Department of Health has the discretion under a finding of rare or unique circumstances to grant exception to the above based on a finding of need of access and quality of care by the program.
- f. Certify that the Applicant will provide educational programs to underserved patient populations (low income, racial and ethnic minorities, women, Medicaid eligible, and handicapped persons) with the goal of decreasing cardiac mortality rates in such populations.
- g. Certify that the applicant will provide a reasonable amount of charity care.
- h. Certify that the applicant will hold monthly multi-disciplinary meetings to evaluate patient outcomes, review quality improvement data, and to identify and implement solutions for any operational issues.
- i. Certify that the following guideline from the Society of Cardiovascular Angiography and Interventions (SCAI)-ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention or such sections' update(s), if applicable, at the time of filing the certificate of need application will be met:
  - (i) Certify the applicant will have available in the catheterization lab the equipment in Section 4.1.1 entitled "Equipment" and that such will be routinely tested;

- (ii) Certify the availability of adequate staff in the catheterization lab as set forth in Section 4.1.2 entitled "Staffing" and that such staff will be certified on both basic life support and advanced cardiovascular life support;
- (iii) Certify that "time-out" procedures will be implemented as discussed in Section 4.1.3 entitled "Time-Out' Procedures"; and
- (iv) Certify that the applicant will operate a quality improvement program and participate in a national PCI registry as discussed in Section 7.1 entitled "Quality Performance: Recommendations"

# Need Criterion 6: Applicants for PCI Services in a Hospital without On-Site Cardiac Surgery Capabilities Currently Providing Diagnostic Catheterization Services

In addition to Need Criteria 1-5, an applicant proposing the establishment of PCI services in a hospital without open heart surgery capabilities, who is already an existing provider of diagnostic catheterization services, shall demonstrate that its diagnostic cardiac catheterization unit has been utilized for a minimum of 300 procedures per year for the two most recent years as reflected in the data supplied to and/or verified by the Mississippi State Department of Health or that its primary operators for the service have a life-time experience of greater than 250 total procedures (including both diagnostic catheterizations and PCIs) with acceptable outcomes after completing a cardiology fellowship. Successful completion of an Interventional Cardiology fellowship is considered adequate certification.

# **Need Criterion 7: Regulatory Approval**

Before utilizing or providing the equipment or service, the applicant desiring to provide the cardiac catheterization equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

# 515.05 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Therapeutic Cardiac Catheterization Equipment and/or the Offering Of Therapeutic Cardiac Catheterization Services

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of therapeutic cardiac catheterization equipment and/or the offering of therapeutic cardiac catheterization services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of therapeutic cardiac catheterization equipment is reviewable if the equipment costs exceed \$1,500,000. The offering of therapeutic cardiac catheterization services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

# **Need Criterion 1: Minimum Procedures:**

An applicant proposing the establishment of therapeutic cardiac catheterization services shall demonstrate that the proposed equipment/service utilization will be a minimum of 450 cardiac catheterizations, both diagnostic and therapeutic, of which at least 100 should be PCIs, per year by its third year of operation.

#### **Need Criterion 2: Staffing Standards**

The applicant shall document that it has, or can obtain, the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs.

#### **Need Criterion 3: Staff Residency**

The applicant shall certify that medical staff performing therapeutic cardiac catheterization procedures shall be onsite within thirty (30) minutes.

#### **Need Criterion 4: Recording and Maintenance of Data**

Applicants shall provide, as required under licensure standards, written assurance that they will record and maintain separate utilization data for diagnostic and therapeutic cardiac catheterization procedures (e.g., morbidity data, number of diagnostic and therapeutic cardiac catheterization procedures performed and mortality data, all reported by race, sex and payor status) and make that data available to the Mississippi State Department of Health annually.

## **Need Criterion 5: Open-Heart Surgery**

An applicant proposing the establishment of therapeutic cardiac catheterization services shall document that open-heart surgery services are available or will be available on-site where the proposed therapeutic cardiac catheterization services are to be offered before such procedures are performed.

#### **Need Criterion 6: Regulatory Approval**

Before utilizing or providing the equipment or service, the applicant desiring to provide the cardiac catheterization equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

# Need Criterion 7: Applicants for Therapeutic Cardiac Catheterization Currently Providing Diagnostic Catheterization Services or PCI Services in a Hospital without On-Site Cardiac Surgery

In additional to Need Criteria 1-6, an applicant proposing the establishment of therapeutic cardiac catheterization services, who is already an existing provider of diagnostic catheterization services and/or PCI services in a hospital without on-site cardiac surgery, shall demonstrate that it has provided a minimum of 300 procedures (including both diagnostic catheterizations and PCIs) per year for the two most recent years as reflected in the data supplied to and/or verified by the Mississippi State Department of Health.

# 516 Open-Heart Surgery

Open-heart surgery, defined as any surgical procedure in which a heart-lung machine is used to maintain cardiopulmonary functioning, involves a number of procedures, including valve replacement, repair of cardiac defects, coronary bypass, heart transplantation, and artificial heart implant.

Section 41-7-191(1)(d), Mississippi Code of 1972, as amended, requires Certificate of Need review for the establishment and/or offering of open-heart surgery services if the proposed provider has not offered such services on a regular basis within twelve (12) months prior to the time the services would be offered.

Table 5-9 presents the utilization of existing facilities. Map 5-2 in the Open Heart Surgery criteria and standards section shows the Cardiac Catheterization/Open-Heart Surgery Planning Areas (CC/OHSPAs) and the location of existing services.

Table 5-9
Number of Open-Heart Surgeries by Facility and Type
By Cardiac Catheterization/Open Heart Surgery Planning Area (CC/OHSPA)
FY 2015 and FY 2016

Methodist Healthcare Olive Branch Hospital CC/OHSPA 2   789   848   0	Facility	County	Number of Adult Open-Heart Procedures		Number of Pediatric Open- Heart Procedures	
Baptist Memorial Hospital - DeSoto   DeSoto   DeSoto   1			2015	2016	2015	2016
Methodist Healthcare Olive Branch Hospital CC/OHSPA 2   789   848   0	CC/OHSPA 1		247	262	1	1
CC/OHSPA 2   Nagnolia Regional Medical Center   Alcom   162   141   0   0   0	Baptist Memorial Hospital - DeSoto		246	261	0	0
Magnolia Regional Medical Center         Alcom         162         141         0         0           North MS Medical Center         Lee         627         707         0         4           CC/OHSPA 3         4		DeSoto			-	
North MS Medical Center					-	-
CC/OHSPA 3		Alcom	162	141	0	0
Delta Regional Medical Center-Main Campus   Washington   4	North MS Medical Center	Lee	627	707	0	4
CC/OHSPA 4   Saptist Memorial Hospital-Golden Triangle Baptist Memorial Hospital-North Mississippi Lafayette	CC/OHSPA 3		4	4	4	4
Baptist Memorial Hospital-Golden Triangle   Lowndes   50   42   0   0   0	Delta Regional Medical Center-Main Campus	Washington	4	4	4	4
Baptist Memorial Hospital-North Mississippi   Lafayette   1   1   4   4	CC/OHSPA 4		51	43	4	4
CC/OHSPA 5         670         653         237         371           Merit Health Central         Hinds         65         46         0         0           MS Baptist Medical Center         Hinds         1         1         4         4           Merit Health River Region         Warren         65         50         4         4           Promise Hospital of Vicksburg         Warren         3         3         4         4           Select Specialty Hospital- Belhaven, LLC         Hinds         2         0         4         0           Select Specialty Hospital- Belhaven, LLC         Hinds         2         0         4         0           Select Specialty Hospital - Gukson         Hinds         311         338         0         0           St. Dominic Hospital         Hinds         311         338         0         0           University of MS Medical Center         Hinds         223         215         221         359           CC/OHSPA 6         145         195         4         4           Anderson Regional Medical Center         Lauderdale         102         142         4         4           Rush Foundation Hospital of Meridian         Lauderdale	Baptist Memorial Hospital-Golden Triangle	Lowndes	50	42	0	0
Merit Health Central         Hinds         65         46         0         0           MS Baptist Medical Center         Hinds         1         1         4         4           Merit Health River Region         Warren         65         50         4         4           Promise Hospital of Vicksburg         Warren         3         3         4         4           Select Specialty Hospital- Belhaven, LLC         Hinds         2         0         4         0           Select Specialty Hospital- Jackson         Hinds         0         0         0         0           St. Dominic Hospital         Hinds         311         338         0         0           University of MS Medical Center         Hinds         223         215         221         359           CC/OHSPA 6         145         195         4         4           Anderson Regional Medical Center         Lauderdale         102         142         4         4           Rush Foundation Hospital of Meridian         Lauderdale         4         53         0         0           The Specialty Hospital of Meridian         Lauderdale         0         0         0         0           CC/OHSPA 7         1	Baptist Memorial Hospital-North Mississippi	Lafayette	1	1	4	4
MS Baptist Medical Center         Hinds         1         1         4         4           Merit Health River Region         Warren         65         50         4         4           Promise Hospital of Vicksburg         Warren         3         3         4         4           Select Specialty Hospital- Belhaven, LLC         Hinds         2         0         4         0           Select Specialty Hospital- Jackson         Hinds         0         0         0         0           St. Dominic Hospital         Hinds         311         338         0         0           University of MS Medical Center         Hinds         223         215         221         359           CC/OHSPA 6         145         195         4         4           Anderson Regional Medical Center         Lauderdale         102         142         4         4           Rush Foundation Hospital         Lauderdale         43         53         0         0           The Specialty Hospital of Meridian         Lauderdale         0         0         0         0           CC/OHSPA 7         1         1         4         4           Southwest MS Regional Med. Center         Pike         1	CC/OHSPA 5		670	653	237	371
Merit Health River Region         Warren         65         50         4         4           Promise Hospital of Vicksburg         Warren         3         3         4         4           Select Specialty Hospital- Belhaven, LLC         Hinds         2         0         4         0           Select Specialty Hospital- Jackson         Hinds         0         0         0         0           St. Dominic Hospital         Hinds         311         338         0         0           University of MS Medical Center         Hinds         223         215         221         359           CC/OHSPA 6         145         195         4         4           Anderson Regional Medical Center         Lauderdale         102         142         4         4           Rush Foundation Hospital         Lauderdale         43         53         0         0           The Specialty Hospital of Meridian         Lauderdale         0         0         0         0           CC/OHSPA 7         1         1         4         4           Southwest MS Regional Med. Center         Pike         1         1         4         4           CC/OHSPA 8         530         467         0 <td>Merit Health Central</td> <td>Hinds</td> <td>65</td> <td>46</td> <td>0</td> <td>0</td>	Merit Health Central	Hinds	65	46	0	0
Promise Hospital of Vicksburg   Warren   3   3   4   4	MS Baptist Medical Center	Hinds	1	1	4	4
Select Specialty Hospital- Belhaven, LLC	Merit Health River Region	Warren	65	50	4	4
Select Specialty Hospital- Jackson   Hinds   0   0   0   0     St. Dominic Hospital   Hinds   311   338   0   0     University of MS Medical Center   Hinds   223   215   221   359     CC/OHSPA 6   145   195   4   4     Anderson Regional Medical Center   Lauderdale   102   142   4   4     Rush Foundation Hospital   Lauderdale   43   53   0   0     The Specialty Hospital of Meridian   Lauderdale   0   0   0   0     CC/OHSPA 7   1   1   4   4     Southwest MS Regional Med. Center   Pike   1   1   4   4     CC/OHSPA 8   530   467   0   0     Forrest General Hospital   Forrest   530   467   0   0     Merit Health Wesley   Lamar   0   0   0   0     CC/OHSPA 9   375   358   0   4     Memorial Hospital at Gulfport   Harrison   186   169   0   4     Ocean Springs Hospital   Jackson   151   151   0   0     Select Specialty Hospital   Gulf Coast   Harrison   0   0   0     Singing River Hospital   Jackson   38   38   0   0	Promise Hospital of Vicksburg	Warren	3	3	4	4
St. Dominic Hospital         Hinds         311         338         0         0           University of MS Medical Center         Hinds         223         215         221         359           CC/OHSPA 6         145         195         4         4           Anderson Regional Medical Center         Lauderdale         102         142         4         4           Rush Foundation Hospital         Lauderdale         43         53         0         0           The Specialty Hospital of Meridian         Lauderdale         0         0         0         0           CC/OHSPA 7         1         1         4         4           Southwest MS Regional Med. Center         Pike         1         1         4         4           CC/OHSPA 8         530         467         0         0         0           Forrest General Hospital         Forrest         530         467         0         0           Merit Health Wesley         Lamar         0         0         0         0           CC/OHSPA 9         375         358         0         4           Memorial Hospital at Gulfport         Harrison         186         169         0         4 <t< td=""><td>Select Specialty Hospital-Belhaven, LLC</td><td>Hinds</td><td>2</td><td>0</td><td>4</td><td>0</td></t<>	Select Specialty Hospital-Belhaven, LLC	Hinds	2	0	4	0
University of MS Medical Center	Select Specialty Hospital- Jackson	Hinds	0	0	0	0
University of MS Medical Center	St. Dominic Hospital	Hinds	311	338	0	0
Anderson Regional Medical Center  Rush Foundation Hospital  Lauderdale  Lauderdale  Lauderdale  Lauderdale  Lauderdale  CC/OHSPA 7  Lauderdale  Lauderdale  CC/OHSPA 8  Forrest General Hospital  Forrest  South Wesley  Lamar  CC/OHSPA 9  Memorial Hospital at Gulfport  CC/OHSPA 9  Memorial Hospital  Lauderdale  Lauderdale  Lauderdale  CC/OHSPA 9  CC/OHSPA 9  CC/OHSPA 9  CC/OHSPA 9  CC/OHSPA 9  CCC/OHSPA	University of MS Medical Center	Hinds	223	215	221	359
Anderson Regional Medical Center         Lauderdale         102         142         4         4           Rush Foundation Hospital         Lauderdale         43         53         0         0           The Specialty Hospital of Meridian         Lauderdale         0         0         0         0           CC/OHSPA 7         1         1         4         4           Southwest MS Regional Med. Center         Pike         1         1         4         4           CC/OHSPA 8         530         467         0         0         0           Forrest General Hospital         Forrest         530         467         0         0           Merit Health Wesley         Lamar         0         0         0         0           Memorial Hospital at Gulfport         Harrison         186         169         0         4           Ocean Springs Hospital         Jackson         151         151         0         0           Select Specialty Hospital         Gulf Coast         Harrison         0         0         0         0           Singing River Hospital         Jackson         38         38         0         0	CC/OHSPA 6		145	195	4	4
Rush Foundation Hospital         Lauderdale         43         53         0         0           The Specialty Hospital of Meridian         Lauderdale         0         0         0         0           CC/OHSPA 7         1         1         4         4           Southwest MS Regional Med. Center         Pike         1         1         4         4           CC/OHSPA 8         530         467         0         0           Forrest General Hospital         Forrest         530         467         0         0           Merit Health Wesley         Lamar         0         0         0         0           CC/OHSPA 9         375         358         0         4           Memorial Hospital at Gulfport         Harrison         186         169         0         4           Ocean Springs Hospital         Jackson         151         151         0         0           Select Specialty Hospital - Gulf Coast         Harrison         0         0         0         0           Singing River Hospital         Jackson         38         38         0         0		Lauderdale	102	142	4	4
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Singing River Hospital Jackson 38 38 0 0						
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	State Total	JUCKSOII	2,812	2,831	254	392

Source: Applications for Renewal of Hospital License for Calendar Year 2015/2016; FY 2016/2017 Annual Hospital Report

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# 516.01 Policy Statement Regarding Certificate of Need Applications for the Acquisition of Open-Heart Surgery Equipment and/or the Offering of Open-Heart Surgery Services

- 1. <u>Service Areas</u>: The need for open-heart surgery equipment/services shall be determined using the nine designated Cardiac Catheterization/Open-Heart Surgery Planning Areas (CC/OHSPAs) presented in this chapter of the Plan. Map 5-2 shows the CC/OHSPAs.
- 2. <u>CC/OHSPA Need Determination</u>: The need for open-heart surgery equipment/services within a given CC/OHSPA shall be determined independently of all other CC/OHSPAs.
- 3. <u>Pediatric Open-Heart Surgery</u>: Because the number of pediatric patients requiring open-heart surgery is relatively small, the provision of open-heart surgery for neonates, infants, and young children shall be restricted to those facilities currently providing the service.
- 4. Present Utilization of Open-Heart Surgery Equipment/Services: MSDH shall consider utilization of existing open-heart surgery equipment/ services and the presence of valid CONs for open-heart surgery equipment/services within a given CC/OHSPA when reviewing CON applications. MSDH shall not consider utilization of equipment/services at any hospital owned and/or operated by the state or its agencies when reviewing CON applications. MSDH may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.
- 5. <u>CON Application Analysis</u>: At its discretion, MSDH may use market share analysis and other methodologies in the analysis of a CON application for the acquisition or otherwise control of open-heart surgery equipment and/or the offering of open-heart surgery services. The Department shall not rely upon market share analysis or other statistical evaluations if they are found inadequate to address access to care concerns.
- 6. Minimum CC/OHSPA Population: A minimum population base of 100,000 in a CC/OHSPA (as projected by the Division of Health Planning and Resource Development) is required before such equipment/services may be considered. The total population within a given CC/OHSPA shall be used when determining the need for services. Population outside an applicant's CC/OHSPA will be considered in determining need only when the applicant submits adequate documentation acceptable to MSDH, such as valid patient origin studies.
- 7. <u>Minimum Caseload</u>: Applicants proposing to offer adult open-heart surgery services must be able to project a caseload of at least 150 open-heart surgeries per year.
- 8. <u>Residence of Medical Staff</u>: Open-heart surgery must be under the control of and performed by personnel living and working within the specific hospital area. No site shall be approved for the provision of services by traveling teams.

# 516.02 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Open-Heart Surgery Equipment and/or the Offering of Open-Heart Surgery Services

MSDH will review applications for a CON for the acquisition or otherwise control of open-heart surgery equipment and/or the offering of open-heart surgery services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures and plans of MSDH; and the specific criteria and standards listed below.

The acquisition or otherwise control of open-heart surgery equipment is reviewable if the equipment cost in excess of \$1,500,000. The offering of open-heart surgery services is reviewable if the proposed provider has not provided those services on a regular basis within twelve (12) months prior to the time such services would be offered, regardless of the capital expenditure.

## **Need Criterion 1: Minimum Population**

The applicant shall document a minimum population base of 100,000 in the CC/OHSPA where the proposed open-heart surgery equipment/service is to be located. Division of Health Planning and Resource Development population projections shall be used.

#### **Need Criterion 2: Minimum Procedures**

The applicant shall demonstrate that it will perform a minimum of 150 open-heart surgeries per year by its third year of operation.

## **Need Criterion 3: Impact on Existing Providers**:

An applicant proposing to acquire or otherwise control open-heart surgery equipment and/or offer open-heart surgery services shall document that each facility offering open-heart surgery services which is (a) in the CC/OHSPA and (b) within forty-five (45) miles of the applicant, has performed a minimum of 150 procedures per year for the two most recent years as reflected in data supplied to and/or verified by MSDH. No hospital owned and/or operated by the state or its agencies shall be considered an existing unit in the CC/OHSPA under this section. MSDH may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.

### **Need Criterion 4: Staffing Requirements**

The applicant shall document that it has, or can obtain, the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs. MSDH staff shall use guidelines presented in Optimal Resources for Examination of the Heart and Lungs: Cardiac Catheterization and Radiographic Facilities, published under the auspices of the Inter-Society Commission for Heart Disease Resources, and Guidelines and Indications for Coronary Artery Bypass Graft Surgery: A Report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Subcommittee on Coronary Artery Bypass Graft Surgery), published under the auspices of the American College of Cardiology, as resource materials when reviewing these items in an application.

# **Need Criterion 5: Staff Residency**

The applicant shall certify that medical staff performing open-heart surgery procedures shall reside within forty-five (45) minutes normal driving time of the facility. The applicant shall document that proposed open-heart surgery procedures shall not be performed by traveling teams.

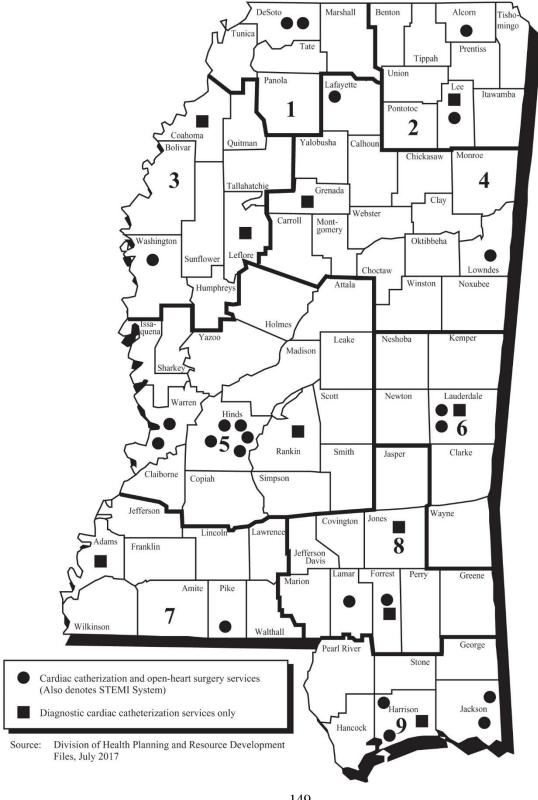
### **Need Criterion 6:Data Requirements**

Applicants shall provide, as required under licensure standards, written assurance that they will record and maintain utilization data for open-heart surgeries (e.g., morbidity data, number of open-heart surgeries performed and mortality data, all reported by race, sex, and payor status) and make such data available to MSDH annually.

# Need Criterion 7: CON Approval/Exemption for Open-Heart Surgery Equipment/Service

Before utilizing or providing the equipment or service, the applicant desiring to provide the open-heart surgery equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by MSDH through a determination of reviewability. Each specified piece of equipment must be exempt from or have CON approval.

Map 5-2 Cardiac Catheterization/Open-Heart Surgery Planning Areas (CC/OHSPA) and Location of Existing/CON-Approved Services



### 517 Systems of Care

There are three systems of care: the Trauma Care System, the ST-Elevation Myocardial Infarction (STEMI) System, and the Stroke System. Mississippi is one of only six states that has multiple acute systems of care, and is the only state that has statewide systems for trauma, STEMI, and stroke.

Each system of care has five key components: an organizational structure, protocols for the transport and transfer of patients, an advisory group process, a performance/quality improvement process, and a data collection system. These components work together to accomplish the ultimate goal of the systems – to deliver the right patient to the right hospital the first time, an approach shown to improve outcomes.

### **518** Emergency Medical Services

In Mississippi, the Emergency Medical Services (EMS) system is extraordinary in that ninety-nine percent (99%) of the state's population is covered by paramedic level agencies. EMS provides services not only to certified prehospital personnel but also provides the highest standards of prehospital healthcare to the citizens and visitors of Mississippi ensuring, patients are delivered to the right hospital the first time.

# 518.01 Organization

The Emergency Medical Services Act of 1973 (Miss. Code Ann. §63-13-11) established standards for the organization of emergency services. Prior to 1974, government involvement in emergency medical services was primarily limited to providing an emergency department in the public hospital. Private operators, predominantly funeral homes, provided emergency transportation.

Within MSDH, the Bureau of Emergency Medical Services organizes, regulates, and maintains a statewide program to improve emergency medical care. Further, it coordinates agency resources in "all-hazard" planning and in response to disasters. This includes incidents involving weapons of mass destruction as well as natural disasters, from hurricanes on the coast to ice storms in the Delta.

EMS Services are typically provided in response to a medical emergency reported through the 9-1-1 system. A 9-1-1 call placed from any telephone is automatically routed to the appropriate designated Public Safety Answering Point (PSAP).

Once the call is received, the nature of the medical emergency is determined, the call is prioritized, appropriate personnel and equipment are dispatched, and pre-arrival instructions are given if appropriate. The dispatcher may ask a number of questions to help assess the nature and severity of the injury or illness. At times the dispatcher may give the caller specific patient care instructions to maximize the success of the injury or illness outcome.

#### 518.02 Protocols

When EMS professionals are called, the injured or ill person is often transported to the hospital in an ambulance. EMS professionals work under protocols approved by physicians designated as Off Line Medical Control. The physician oversees the care of patients in EMS systems, and is knowledgeable about out-of-hospital patient care interventions and delivery systems. Typically the physicians work in conjunction with local EMS managers to assure quality patient care. EMS may be provided by a fire

department, a private ambulance service, a county or government-based service, a hospital-based service, or a combination of the above. EMS professionals may be paid or serve as volunteers in the community.

# 518.03 Advisory Group

In accordance with Miss. Code Ann. § 41-59-7, the Emergency Medical Services Advisory Council (EMSAC) was created, with membership appointed by the Governor.

## **518.04 Performance Improvement**

The Medical Directors' Training and Quality Assurance (MDTQA) Committee provides performance improvement review of the EMS system and develops model protocols for adoption by EMS services. The committee is chaired by the State EMS Medical Director, a board-certified emergency physician, and membership includes physicians who provide medical control to EMS services, and EMS practitioners.

#### 518.05 Data System

The Mississippi EMS Information System (MEMSIS) uses a web-based system hosted by ImageTrend. The ImageTrend EMS State Bridge is a pre-hospital emergency data collection, analysis and reporting system. EMS State Bridge integrates information across the entire emergency medical community, whether in the ambulance, the local station, or state offices. With the EMS State Bridge, ambulance services are able to satisfy reporting requirements easily, without major investment and without learning complex new technology. 153155

The system provides for:

- Data collection based upon the NHTSA V2.2.1 data set. Data will be migrated to the NHTSA V3.4 data set in FY2018.
- The aggregation of information from various units and services with the possibility of sharing secured data with other systems and agencies.
- Electronic transport of information to improve communications.
- Standard and ad hoc reporting for using data to support evidence based practices.
- Easy expansion through its open architecture as needs grow and evolve.
- Scalability to conform to the needs of small, medium and large services as required.

Additionally, the system is HIPAA compliant and sensitive to medical data security issues. The application meets and exceeds state and federal data privacy requirements.

# 519 Mississippi Trauma Care System

Trauma is the leading cause of death for all age groups in Mississippi from birth to age forty-four (44). Serious injury and death resulting from trauma events such as vehicle crashes, falls, and firearms claim 500 lives and disable 6,000 Mississippians each year. Trauma victims require immediate, expert attention.

# 519.01 Organization

Miss. Code Ann. §41-59-5 (5), establishes MSDH as the lead agency to develop a uniform, non-fragmented, inclusive statewide Trauma Care System, that provides excellent patient care. Through the State Trauma Plan, MSDH has designated seven trauma care regions; each incorporated as a 501c-3

organization which contracts with MSDH to administer the plan within their respective region. The State Trauma Plan includes the seven regional plans, allows for transfer protocols between trauma facilities, and for trauma patients to be transported to the "most appropriate" trauma facility for their injuries.

To increase participation in the Trauma Care System, the Mississippi Legislature enacted legislation (House Bill 1405) in 2008, which required MSDH to develop regulations mandating all licensed acute-care facilities participate in the Mississippi Trauma Care System ("Play or Pay"). Hospitals must participate at a level commensurate with their capabilities, or pay a non-participation fee to the Trauma Care Trust Fund. Each hospital's capability to participate in the Trauma Care System is reviewed annually by their respective Trauma Care Region and MSDH, which determines the appropriate level of participation and any associated fee.

Trauma facility designation levels set specific criteria and standards of care that guide hospital and emergency personnel in determining the level of care a trauma victim needs, and whether that hospital can care for the patient or transfer the patient to a trauma center that can administer more definitive care.

Level I Trauma Centers must have a full range of trauma capabilities, including an emergency department, a full-service surgical suite, intensive care unit, and diagnostic imaging. Level I centers must have a surgical residency program, ongoing trauma research, and provide 24-hour trauma service. These hospitals provide a variety of other services to comprehensively care for both trauma patients. Level I Trauma Centers act as referral facilities for Level II, III, and IV Trauma Centers. The University of Mississippi Medical Center (UMMC) in Jackson is the only Level I facility in the state. Two Level I Trauma Centers border the northern and southeastern part of the state and are located in Tennessee and Alabama. Additionally, a "stand-alone" Tertiary Pediatric Trauma Center located in Tennessee participates in the system.

**Level II Trauma Centers** must be able to provide comprehensive care to the severely injured patient. These facilities must have a full range of trauma capabilities, including an emergency department, a full service surgical suite, an intensive care unit, and diagnostic imaging. Level II Trauma Centers act as referral facilities for Level III and IV Trauma Centers.

**Level III Trauma Centers** must offer general/trauma surgery and orthopedic surgery and have the ability to manage the initial care of multi-system trauma-patients. Transfer-protocols must be in place with Level I and II Trauma Centers for patients that exceed the Level III Trauma Center's resources.

**Level IV Trauma Centers** provide initial evaluation and assessment of injured patients. Most patients will require transfer to facilities with more resources dedicated to providing optimal care for the injured patients. Level IV Trauma Centers must have transfer protocols in place with Level I, II, and III Trauma Centers.

#### 519.02 Protocols

The Trauma Care System has developed uniform trauma activation criteria for all hospitals participating in the system to insure that patients receive appropriate care, regardless of locale. EMS Field Destination Guidelines, based on the Center for Disease Control (CDC) Field Triage Decision Scheme, provide for the transport of trauma patients to the most appropriate facility. The approved Trauma Activation Criteria, based on the publication *Resources for Optimal Care of the Injured Patient*, provide the criteria used by trauma center staff for trauma team activation.

# 519.03 Advisory Committee

In accordance with Miss. Code Ann. § 41-59-7, the Mississippi Trauma Advisory Committee (MTAC) was created as a committee of the Emergency Medical Services Advisory Council (EMSAC). This committee is comprised of members of EMSAC, appointed by the Governor. The committee acts as the advisory body for trauma care system development, and provides technical support to MSDH in all areas of trauma care system design, trauma standards, data collection and evaluation, continuous quality improvement, trauma care system funding, and evaluation of the trauma care system and trauma care programs.

## **519.04 Performance Improvement**

A systems approach to trauma care provides the best means to protect the public from pre-mature death and prolonged disability. The development of a statewide system of care for the injured must include a mechanism to monitor, measure, assess, and improve the processes and outcome of care. The process must be a continuous, multidisciplinary effort to reduce inappropriate variation in the care of trauma patients, and improve the effectiveness of the system and its components, including pre-hospital care (communication, dispatch, medical control, triage, and transport), hospital care, inter-facility management, rehabilitative care, and mass casualty disaster response.

Statewide Performance Improvement (PI) consists of multiple layers of continuous monitoring and evaluation of treatment processes to identify opportunities to optimize care and improve outcomes. The continuous cycle of evaluation extends from the PI programs of EMS providers and hospitals to review committees established at the regional and state levels.

The State Trauma PI Committee is appointed by the MSDH Director of Health Protection. The committee is independent from MTAC and EMSAC. The PI Committee is chaired by the state Trauma System of Care Medical Director. Membership shall include, but may not be limited to, representatives from the following areas:

- Emergency Medicine
- State EMS PI Committee
- Trauma Registry Committee
- One representative from each Trauma Care Region
- Nursing representative from each Trauma Center level
- Tertiary Pediatric Trauma Center
- Trauma Medical Directors from each Level I Trauma Center

The PI Committee establishes specific statewide performance measures. Subject Matter Experts (SME) participate in committee activities appropriate to their expertise. MSDH Division of Trauma provides administrative support to the PI Committee and all meetings of the Committee, PI Committee meetings are by invitation only and are not open to the public.

## 519.05 Data System

There are four objectives of the trauma registry: performance improvement, enhanced hospital operations, injury prevention, and medical research. In July 2006, MSDH deployed "Collector" Trauma Registry software to all hospitals that participated in the Mississippi Trauma Care System. Today, every Mississippi licensed acute care facility (hospital) having an organized emergency service or department uses the Collector software to submit their data to the State Trauma Registry.

Collector is a trauma registry system that helps users meet changing requirements of collection and evaluation of trauma data for quality assurance, accreditation, management, prevention and research. Collector is a complete data management and report generating package which includes a user friendly data entry and verification system, querying capabilities and integration with expert coding software. Collector offers coding, database and analysis capabilities.

In addition to its use as the trauma registry, Collector is also used as the state's burn registry and the registry for Traumatic Brain and Spinal Cord Injuries (TBI/SCI).

# **520 STEMI System of Care**

ST-elevation myocardial infarction (STEMI) is a significant public health problem and carries a high risk of death and disability. The American Heart Association (AHA) estimates that as many as 400,000 people will suffer from a STEMI heart attack each year in the United States. Mississippi currently leads the nation in mortality and morbidity from cardiovascular disease.

STEMI patients should be recognized as quickly as possible to identify those eligible for thrombolytic or primary PCI therapy. Research has shown that both morbidity and mortality can be reduced by the approach of rapid interventional reperfusion within ninety (90) minutes of hospital arrival. Additional research has demonstrated that in-the-field recognition by pre-hospital providers utilizing 12-lead ECG, coupled with pre-hospital notification of the receiving facilities, can further reduce time to reperfusion, resulting in improved outcomes.

### 520.01 Organization

The STEMI System of Care is a voluntary system comprised of a number of separate components, which are organized and work together, as a system. The individual components and elements are described below:

- STEMI Regions This component facilitates system organization, coordination, and education requirements for both practitioners and the public. Each STEMI Region (North, Central, and South) will have a regional STEMI Coordinator, who will schedule and facilitate quarterly regional meetings.
- Pre-Hospital Component EMS units are an integral part of the STEMI System. All EMTs, Paramedics, on-line and off-line medical control physicians need to have a basic knowledge and awareness of the STEMI System Plan elements and system function. Specifically, this knowledge refers to the alert criteria (identification of a STEMI), and communication procedures.
- Hospital Component Hospitals may participate in the STEMI System on a voluntary basis, but must meet the criteria prescribed in the STEMI Standards to be designated as a STEMI Receiving or STEMI Referral Center.
- Program oversight is provided by MSDH's Bureau of Acute Care Systems.

Map 5-2 identifies those hospitals participating in the STEMI System.

#### 520.02 Protocols

Standard treatment protocols for both STEMI Receiving Centers and STEMI Referral Centers have been developed and published by the Mississippi Healthcare Alliance (MHCA), the

practitioners' organization which initiated the development of the system of care. The current protocols may be found on the MHCA website at: http://mshealthcarealliance.org/.

# 520.03 Advisory Group

The STEMI Advisory Committee meets quarterly. Membership is compromised of the following membership categories as prescribed by the STEMI System of Care Plan:

- Cardiology Co-Chairman
- Emergency Medicine Co-Chairman
- Emergency Medicine Representative Northern Region
- Emergency Medicine Representative Central Region
- Emergency Medicine Representative Southern Region
- Emergency Nursing Representative Northern Region
- Emergency Nursing Representative Central Region
- Emergency Nursing Representative Southern Region
- Hospital Administration Representative Northern Region
- Hospital Administration Representative Central Region
- Hospital Administration Representative Southern Region
- Cardiology Representative Northern Region
- Cardiology Representative Central Region
- Cardiology Representative Southern Region
- STEMI Nursing Representative Northern Region
- STEMI Nursing Representative Central Region
- STEMI Nursing Representative Southern Region
- Southern Regional STEMI Coordinator
- Registry Representative Northern Region
- Registry Representative Central Region
- Registry Representative Southern Region
- EMS Provider Representative Northern Region
- EMS Provider Representative Central Region
- EMS Provider Representative Southern Region
- EMS Administration Representative Northern Region
- EMS Administration Representative Central Region
- EMS Administration Representative Southern Region
- Northern Regional STEMI Coordinator
- Central Regional STEMI Coordinator
- Southern Regional STEMI Coordinator
- American Heart Association Representative

### **520.04 Performance Improvement**

Statewide Performance Improvement (PI) consists of multiple layers of continuous monitoring and evaluation of treatment processes to identify opportunities to optimize care and improve outcomes. The continuous cycle of evaluation extends from the PI programs of EMS providers and hospitals to review committees established at the regional and state levels.

The STEMI PI Committee meets quarterly. Membership is comprised of the following:

- Cardiology Chair
- Emergency Medicine Vice Chair
- Cardiologist(one from each region)
- Emergency Department Physician (one from each region)
- Representative from each PCI hospital (minimum of one per region)
- Non-PCI hospital representative (minimum of one per region)
- EMS Representatives (minimum of three)

The PI Committee establishes specific system-wide performance measures. Subject Matter Experts (SME) participate in committee activities appropriate to their expertise. The MSDH Bureau of Acute Care Systems provides administrative support to the PI Committee and all meetings of the Committee. PI committee meetings, are by invitation only, and are not open to the public.

# 520.05 Data System

The data system for the STEMI System of Care is the ACTION Registry-GWTG (Get With The Guidelines) system. The ACTION Registry-GWTG is a risk-adjusted, outcomes-based quality improvement program that focuses exclusively on high-risk STEMI/NSTEMI patients. It helps hospitals apply American College of Cardiology (ACC) and American Heart Association (AHA) clinical guideline recommendations in their facilities, and provides invaluable tools to measure care and achieve quality improvement goals. Use of the ACTION Registry-GWTG is a requirement for participation in the STEMI System of Care.

# 521 Acute Ischemic Stroke System of Care

Mississippi ranks fourth in the nation in occurrence of death from the immediate and long-term effects of stroke. Moreover, stroke continues to be the fifth leading cause of death and a leading cause of disability in Mississippi. However, eighty-three percent (83%) of stroke occurrences in Calendar Year 2015 were potentially treatable ischemic strokes. The primary goal of the Mississippi Stroke System of Care is to get the patient suffering from a stroke to an appropriate hospital so that patients who are candidates for thrombolytic and interventional therapies may receive appropriate care in a timely manner. This approach is supported by research that shows early thrombolytics for ischemic stroke and interventional therapy for large vessel occlusion improve outcomes in patients suffering from these types of stroke. Therefore, the Stroke System of Care has focused on early recognition of strokes by educating individuals to call 911 when a stroke occurs, minimizing door to CT times and ensuring early administration of thrombolytics.

In Mississippi, most of the specialty physicians, like neurologists, are located in select large medical centers; therefore, access to a stroke specialist is a primary concern in stroke care. Unlike trauma and STEMI systems of care, where it is essential to get the patient to a specialty facility in the shortest amount of time, stroke care can be initiated at a rural facility in conjunction with input from a nurse practitioner trained in stroke care, either by telephone or telemedicine. A careful patient history and examination, laboratory analysis, and a head CT can be done at "Stroke-Ready" hospitals, allowing the timely decision to treat the patient with thrombolytic therapy at that hospital before transfer to a "Stroke Center" ("Drip and Ship") if needed for neurological, neurosurgical, or neuro-interventional support.

#### 521.01 Organization

The Stroke System of Care is a voluntary system comprised of a number of separate components, which are organized and work together, as a system. The individual components and elements are described below:

- Stroke Regions This component facilitates system organization, coordination, and education requirements for both practitioners and the public. Each Stroke Region (North, Central, and South) will have a regional Coordinator, who will schedule and facilitate quarterly regional meetings.
- Pre-Hospital Component EMS units are an integral part of the STEMI System. All EMTs and paramedics need to have a basic knowledge and awareness of the Stroke System elements and system function. Specifically, this knowledge refers to entry criteria (identification of an acute ischemic stroke), triage and destination guidelines, and communication procedures. On-line and off-line medical control physicians will also need to be involved with the Stroke System elements and system function.
- Hospital Component Hospitals may participate in the Stroke System on a voluntary basis.
- Program oversight is provided by MSDH's Bureau of Acute Care Systems.

#### **521.02 Protocols**

Standard treatment protocols for Stroke Ready and Non-Stroke hospitals have been developed and published by the Mississippi Healthcare Alliance (MHCA), the practitioners' organization which initiated the development of the system of care. The current protocols may be found on the MHCA website at: http://mshealthcarealliance.org/.

The protocols are centered on the "Drip and Ship" model, where outlying hospitals identify the presence of an acute ischemic stroke through a head CT, and initiate thrombolytic therapy (tPA-Alteplase) prior to transferring the patient to a Stroke Center. EMS protocols include the use of the Cincinnati Stroke Scale to identify potential stroke victims, and their delivery to a Stroke Ready hospital for diagnosis.

#### 521.03 Advisory Group

The Stroke Advisory Committee meets quarterly. Membership is compromised of the following as prescribed in the Stroke System of Care Plan:

- Chairperson
- Emergency Medicine Representative Northern Region
- Emergency Medicine Representative Central Region
- Emergency Medicine Representative Southern Region
- Emergency Nursing Representative Northern Region
- Emergency Nursing Representative Central Region
- Emergency Nursing Representative Southern Region
- Hospital Administration Representative Northern Region
- Hospital Administration Representative Central Region
- Hospital Administration Representative Southern Region
- Neurology Representative Northern Region
- Neurology Representative Central Region
- Neurology Representative Southern Region
- Stroke Nursing Representative Northern Region
- Stroke Nursing Representative Central Region

- Stroke Nursing Representative Southern Region
- Registry Representative Northern Region
- Registry Representative Central Region
- Registry Representative Southern Region
- EMS Provider Representative Northern Region
- EMS Provider Representative Central Region
- EMS Provider Representative Southern Region
- EMS Administration Representative Northern Region
- EMS Administration Representative Central Region
- EMS Administration Representative Southern Region
- Northern Regional STROKE Coordinator
- Central Regional STROKE Coordinator
- Southern Regional STROKE Coordinator
- American Heart Association Representative

## **521.04 Performance Improvement**

Statewide Performance Improvement (PI) consists of multiple layers of continuous monitoring and evaluation of treatment processes to identify opportunities to optimize care and improve outcomes. The continuous cycle of evaluation extends from the PI programs of EMS providers and hospitals to review committees established at the regional and state levels.

The Stroke PI Committee meets quarterly and is appointed by the State Health Officer. Membership is comprised of the following:

- Neurology Chair
- Emergency Medicine Vice Chair
- Neurologist (one from each region)
- One Emergency Department Physician (one from each region)
- Representative from each stroke participating hospital (minimum of one per region)
- EMS representative (minimum of three)

Subject Matter Experts (SME) participate in committee activities appropriate to their expertise. The MSDH Bureau of Acute Care Systems provides administrative support to the PI Committee and all meetings of the Committee. PI Committee meetings are by invitation only and are not open to the public.

# 521.05 Data System

The American Heart Association/American Stroke Association GWTG (Get With The Guidelines) – Stroke Program is a performance improvement program for hospitals that uses a stroke registry to support its aims. GWTG-Stroke collects patient level data on characteristics, diagnostic testing, treatments, adherence to quality measures, and in-hospital outcomes on patients hospitalized with stroke and transient ischemic attack (TIA). Collection of comprehensive, continuous stroke data supports data analysis and the development of interventions to improve stroke care.

The primary goal of GWTG-Stroke program is to improve the quality of care and outcomes for patients hospitalized with stroke and TIA. The GWTG-Stroke registry helps achieve this goal in a variety of ways, including:

- Enabling high caliber stroke research;
- Promoting stroke center designation;
- Supporting hospital level quality improvement; and
- Driving the creation of a regional stroke system

Map 5-3 Mississippi Trauma Care Regions

